Short Term Outcomes of Patients with Acute Stroke after Thrombolysis:
A Retrospective Comparative Case Series

2019 Legislative Priorities

Advocacy
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Maryland Pharmacist

WINTER 2019

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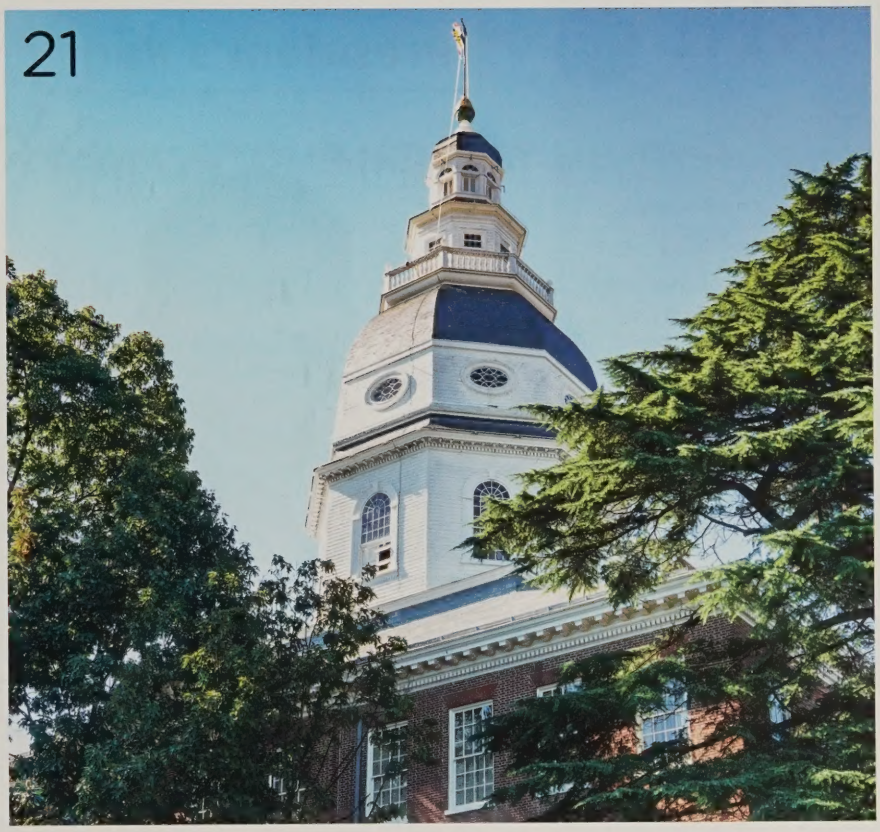

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President's Pad

Dear MPhA Members,

I hope everyone is energized and ready because the association is kicking off an action-packed 2019! Those of you keeping up with our social media and Monday Message communications know that the schedule is full of new events and updates. From our perennial Mid-Year Meeting at the College Park Marriott Hotel and Conference Center to a web-based CE on LGBTQ Health, the association is aiming to bring more value to you to meet your educational and professional needs. As I begin the second half of my presidency, I am excited for the enhancements our committees have implemented to bring pharmacists and student pharmacists together using both live and virtual modalities.

Our committees continue to complete their charges and, in many cases, focus on going above and beyond to achieve additional priorities. Please keep an eye out for new webinars as well as events focused on expanding the association's reach to our technicians, student pharmacists, and seasoned professionals. Our association's history will also be showcased this Fall through an auction to benefit the MPhA Foundation as well as a Founder's Day event. Even a well-established event like the Annual Convention, which will take place in Ocean City this year, will play host to a new interactive mentorship program that you have the opportunity to participate in. Through repeated innovation, we continue to leverage our existing offerings to create a platform for your involvement.

If you have not had the opportunity to attend one of our monthly Board of Trustee or committee meetings, I encourage you to consider participating. Many of these meetings are also offered via the web or teleconferencing, and it is an easy method of enhancing your connection to the association. Many of the innovations you may have noticed this year have come from our newest members; you know how the association can serve you and your fellow pharmacists in a better capacity. As a member, you are also empowered to participate in our House of Delegates and vote during our annual elections. Our association board exists to serve you; I strongly encourage you to take the time to review our slate of candidates and vote this year. It is your voice that will continue to drive the evolution of this association to meet the needs of Maryland pharmacists and patients.

I would be remiss if I did not mention the importance of advocating for our profession, particularly during the legislative session of the Maryland General Assembly. As you may know, the Maryland Pharmacists Association is part of the Maryland Pharmacy Coalition and supports the organization of the annual Legislative Day event in Annapolis. We have a new set of elected representatives to educate this year; your support is greatly valued and appreciated so that they can make educated decisions for the benefit of our patients and our livelihoods. Please consider volunteering your time to offer testimony or to educate a legislator. It makes an incredible difference as the hard-won legislative successes in recent years have been built upon your support for your profession.

Thank you for reading, and I look forward to sharing updates in our next journal.

Chai Wang

Chai Wang, PharmD, BCPS, AE-C
President, Maryland Pharmacists Association 2018-2019

MPhA Welcomes OUR NEWEST MEMBERS

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SAVE THE DATES IN YOUR 2019 CALENDAR

Feb 28 — **Membership Committee Meeting**

Mar 1 — **Deadline for MPhA & MPhA Foundation Scholarships**

Mar 2019 — **2nd Quarter Webinar: Community Pharmacy Partnerships for Transitions of Care**

Mar 11 — **Professional Development Committee Meeting**

Mar 14 — **Board of Trustees Meeting**

Apr 1 — **Deadline for MPhA Awards**

For more information and additional activities, visit www.marylandpharmacist.org.

Member Mentions & News You Can Use

Member Advocates for Drug Transparency

MPhA Member Surinder Singal and Executive Director Aliyah Horton discuss the challenges facing independent pharmacies and the need for drug cost transparency in a recent Calvert Recorder article.

"Community pharmacy is a benefit to residents of Maryland. They serve as a triage point and provide services that [chain pharmacies] don't, especially in rural communities," Horton said. "With the way they are getting reimbursed, they are going out of business by just doing their job." Read the full article at http://ow.ly/TESt30nhqmG.

Lin and Truong Appointed to AACP Leadership Roles

Congratulations to two MPhA members elected to leadership positions with the American Association of Colleges of Pharmacy (AACP): Anne Y. Lin. PharmD was elected as President-Elect and Hoai-An Truong, PharmD was elected as Chair-Elect of the Continuing Professional Development Section. Dr. Linn is with the Notre Dame of Maryland School of Pharmacy and Dr. Truong is with the University of Maryland Eastern Shore. Congrats to Anne and Hoai-An!

Rusinko and Garmer Appointed to BOP

Kristopher Rusinko, PharmD was recently appointed as the Home Infusion Representative on the Maryland Board of Pharmacy. He will be serving his first term through April 20, 2022. Kristopher is the Director of Operations at Johns Hopkins Home Care Group Pharmacy Services. George Garmer, owner of Halethorpe Pharmacy and Independent Drug, was also appointed to serve in the Independent seat for the same term. Congrats Kristopher and George!

And thank you to fellow MPhA member Roderick Peters, who recently completed his service as an Independent Pharmacy Representative on the Board.

Lee Featured in PharmacyToday

The November issue of PharmacyToday featured our very own Kinbo Lee, PharmD, MHS! In the feature, Kinbo discusses why he loves being a pharmacist and gives advice to his fellow pharmacist colleagues.

Kinbo is the co-chair of the MPhA Federal Pharmacy Network and a member of the MPhA Foundation Board. Read the feature at https://bit.ly/2CmwoWO.

APhA CEO for a Day

MPhA President Chai Wang, PharmD, BCPS, AE- C had the honor of serving at APhA's "CEO for the Day" this past October. Chai met with APhA CEO Tom Menighan at the headquarters in Washington, DC and visited legislators with APhA staff to advocate for provider status.

Photo courtesy APhA Foundation

Study Groups for BPS Board Certification

Interested in studying for Board of Pharmacy Specialties (BPS) board certification? Would you be interested in forming study groups to prepare for the board certification exam? If you're interested in joining, please email Eriny Victor at erinyv@gmail.com to get conference call information.

Yankellow Awards Icon Honor

Congratulations to Dr. Ellen H. Yankellow of Correct Rx Pharmacy Services, Inc. for being named one of the 2018 Icon Honors winners! *The Daily Record* presents the annual Icon Honors awards to recognize Maryland business leaders over the age of 60 for their notable success and demonstration of strong leadership both within and outside of their chosen field.

The 2018 award winners were honored at a dinner in December. Congrats Ellen!

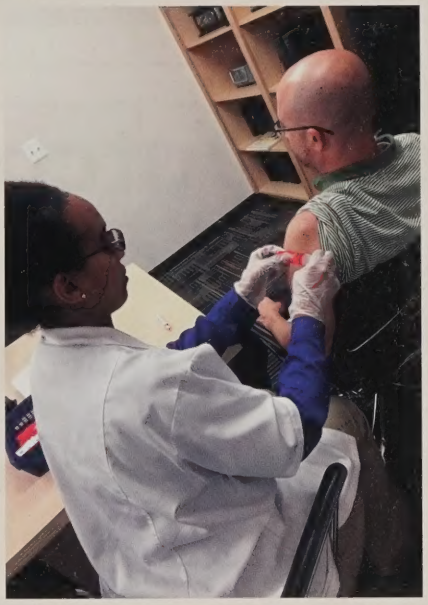
Mattingly Appointed to APhA Journal Editorial Board

Joey Mattingly, PharmD, assistant professor of pharmacy practice and sciences, has been appointed to the APhA Editorial Board of the journal Pharmacoeconomics — Open. Congrats Joey!

MPhA Flu Shot Clinic

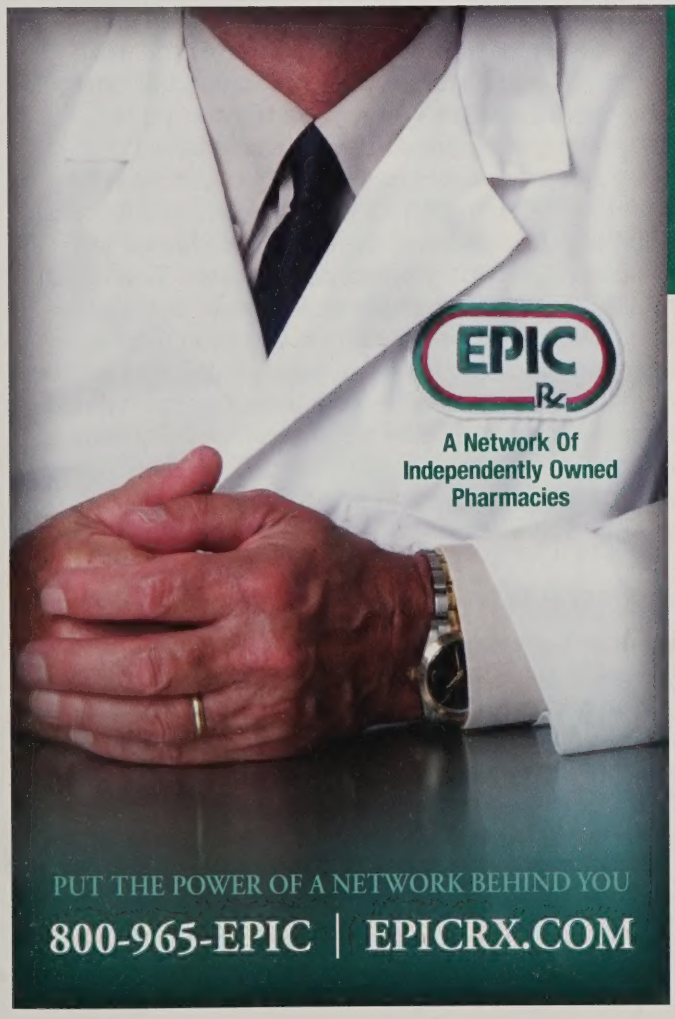
MPhA held a Flu Shot Clinic last October at our headquarters in Columbia. We welcomed many of our business park colleagues to the MPhA offices to get their flu shot and educate them on the pharmacy community!

Special thank you to Walgreens for providing a volunteer pharmacist for the event! And we were happy to see that our pharmacist was none other than Dr. Hanna Fenta, a former Notre Dame of Maryland University School of Pharmacy student and APhA-ASP representative to the MPhA Board.



Holiday Food Drive Was a Success!

Thank you MPhA members and friends who donated items at our December holiday party. A full shopping cart of food was delivered to the Manna Food Center in Montgomery County. We thank you for your generous spirit!



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Editorial

Short Term Outcomes of Patients with Acute Stroke after Thrombolysis:

A Retrospective Comparative Case Series

Scott Baker, PharmD; Patrick Dougherty, PharmD, BCPS

All authors involved with this research have read and reviewed the MPhA journal submission guidelines and have no conflicts of interest to disclose.

Purpose

To determine if there is a significant effect on short-term mortality and morbidity based on the time from initial symptom onset to the time of alteplase administration.

Background

Alteplase is indicated for acute ischemic stroke within three hours of symptom onset, and the American Heart Association/American Stroke Association (AHA/ASA) recommends its use up to 4.5 hours after symptom onset in certain clinical circumstances.[1] The AHA/ASA's guidelines for the early management of patients with acute ischemic stroke suggest administering alteplase IV as soon as possible in cases of acute ischemic stroke.[1] Patient benefits of alteplase are well-established with regard to long-term mortality and ultimate level of disability caused by ischemic stroke.[1,2] Data focusing on how a more timely administration of alteplase affects more immediate outcomes involving mortality and morbidity in patients with acute ischemic stroke is limited.

Study Design

Retrospective, single-centered, community hospital-based comparative case series.

Methods

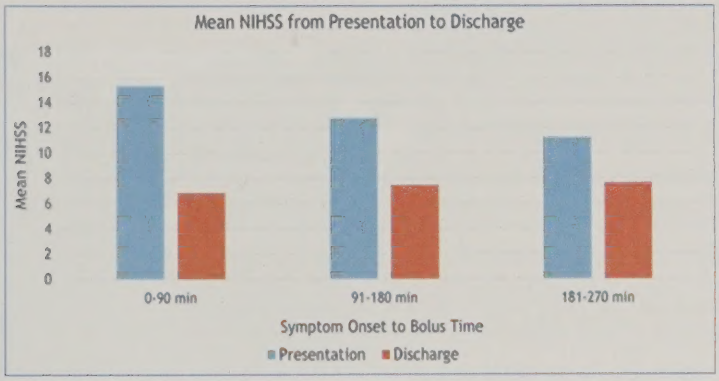
123 patients receiving alteplase for acute ischemic stroke from January 1, 2014 to December 31, 2017 were reviewed. Patients were included if they had documentation for time of both initial symptom onset and intravenous alteplase administration and documentation of National Institute of Health Stroke Scale (NIHSS) score at both presentation and discharge. Patients were excluded if they were transferred to another facility. Comparisons were made based on whether symptom onset to alteplase bolus time fell between 0 to 90 min, 91 to 180 min, or 181 to 270 min. The primary outcome was the mean net change in NIHSS score. Secondary outcomes included 30 and 90 day stroke-related readmissions, 30 and 90 day all-cause readmissions, final patient disposition (home, rehabilitation facility, long-term care, death), and length of stay (LOS). A stroke-related readmission was defined as a readmission caused by a symptom or complication secondary to the stroke; these included falls secondary to balance issues, aspiration pneumonia secondary to dysphagia, and recurrent acute ischemic stroke.

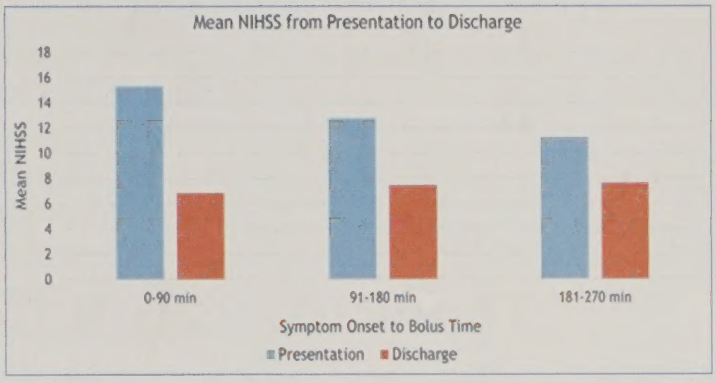
Statistical Analysis

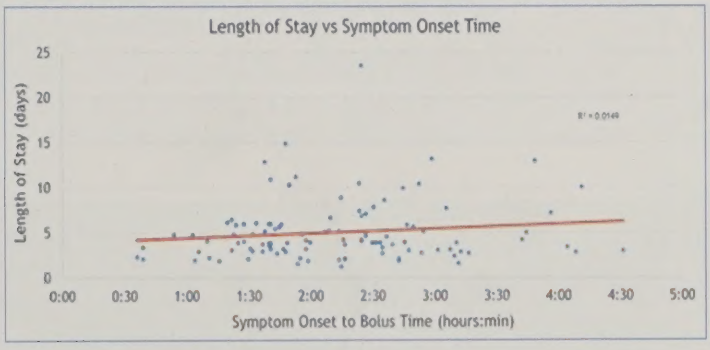
Differences between the 0-90 minute, 91-180 minute, and 181–270 minute groups in regard to mean NIHSS reduction and mean LOS were analyzed using a one-way ANOVA test. Differences in regard to the four types of readmission rates were analyzed based on chi-square analyses. Finally, differences in ultimate disposition of the patient were analyzed with a Kruskal-Wallis test using the assumption that the dispositions were an ordinal progression in the following order: home, rehabilitation facility (rehab), long-term care facility (LTC), hospice, and death.

Results

Outcome	0–90 min (n=22)	91–180 min (n=81)	181–270 min (n=20)	p-value
Mean net change in NIHSS score	- 8.5	- 5.3	- 3.6	0.19
30-day stroke-related readmission	1 (4.5%)	7 (8.6%)	0 (0.0%)	0.66
90-day stroke-related readmission	1 (4.5%)	13 (16.0%)	1 (5.0%)	0.19
30-day all-cause readmission	2 (9.1%)	8 (9.9%)	2 (10.0%)	0.99
90-day all-cause readmission	2 (9.1%)	16 (19.8%)	4 (20.0%)	0.49
Mean LOS	3.8 days	5.4 days	4.7 days	0.17







Discussion

This study faced several significant limitations, namely the following: 1) Only readmission data from the community hospital at which patients were initially admitted for acute ischemic stroke was accessible; therefore, readmissions could potentially be under-represented. 2) In some cases during the earlier years of the study timeframe, the initial NIHSS scores were calculated by nurses rather than the physician. In other cases, the score was calculated by both a nurse and a physician with some minor discrepancies noted between two scores for the same patient. 3) The NIHSS tends to have more inter-rater variability than other stroke severity scoring systems;[3] however, it is the only scale that was consistently used on the majority of patient charts examined. 4) There were approximately four times as many patients in the 91–180 minute group compared to the other two groups. Considering this in addition to a relatively small sample size detracts from the power of this retrospective analysis.

The 2018 AHA/ASA stroke management guidelines make clear that alteplase should be administered as soon as possible in eligible patients, even making recommendations that emergency departments set goals for door-to-needle times of less than 60 minutes and less than 45 minutes for 50% of patients.[1] Furthermore, administering alteplase as soon as possible theoretically makes sense given the "time equals tissue" mantra, and several studies have demonstrated the long-term mortality benefit of early alteplase administration.[1] This study aimed to provide evidence on more immediate outcomes that could theoretically benefit from early alteplase administration.

Despite some positive correlation and trends between early alteplase administration (0–90 minutes from symptom onset) and both a greater reduction in NIHSS score and shorter LOS, statistical significance was not met. Perhaps increasing the sample size of patients and having more evenly distributed groups would lead to statistical significance. This study covered a four year

span of acute ischemic stroke admissions through the emergency department. Over the course of this four year period, the department's mean door-to-needle time improved, hence the majority of patients in the 0–90 minute group came from the last two years of data reviewed. A continuation of this more rapid door-to-needle time will provide more patients for the 0–90 minute group, allowing for a more fair statistical analysis to be performed.

Conclusions

Though the difference in mean NIHSS score reduction is not statistically significant, the data suggests a correlation between decreasing symptom onset to alteplase bolus time and a greater reduction in NIHSS score from presentation to discharge. This could be clinically significant, though further research is needed with a larger patient population before more absolute conclusions can be drawn on the more immediate outcomes of timelier alteplase administration. Regardless, the trends shown in this small data set support the recommendations made by the AHA/ASA stroke guidelines for administration of alteplase in eligible patients with acute ischemic stroke as soon as possible. ●

REFERENCES

1. Powers WJ, Rabinstein AA, Ackerson T, et al; on behalf of the American Heart Association Stroke Council. 2018 Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2018;49:e46–e99. doi: 10.1161/STR.0000000000000158.
2. Emberson J, Lees KR, Lyden P, Blackwell L, et al. Effect of treatment delay, age, and stroke severity on the effects of intravenous thrombolysis with alteplase for acute ischaemic stroke: a meta-analysis of individual patient data from randomised trials. *Lancet* (2014) 384:1929–35.10.1016/S0140-6736(14)60584-5
3. Ghandehari K. Challenging comparison of stroke scales. J Res Med Sci. 2013;32:906–910.

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June 21–24, 2019

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Highlights include:

- CEs on the most current trends in the pharmacy profession
- Opportunities to network, connect, and re-connect with your peers
- Chances to gain new perspectives from our dynamic speakers
- Recognition of professional accomplishments
- Social activities all ages can enjoy

Hotel Information

The Clarion Resort Fontainebleau is offering discounted hotel rates for MPhA attendees. To reserve your room, call the Clarion directly at 1-800-638-2100. You must tell the reservation agent you are with the Maryland Pharmacists Association to receive the special rate. The deadline is Monday, May 20, 2019.

Interested in exhibiting or sponsorship?

Contact Lauren Williams at lauren.williams@mdpha.com or 443-583-8000

Editorial

Expanding Pharmacists' Prescriptive Authority: Tobacco Cessation Aids

Krystalyn Weaver, PharmD, National Alliance of State Pharmacy Associations

Pharmacists in Maryland may soon join a growing number of states that allow pharmacists to prescribe medications to assist patients to quit smoking.

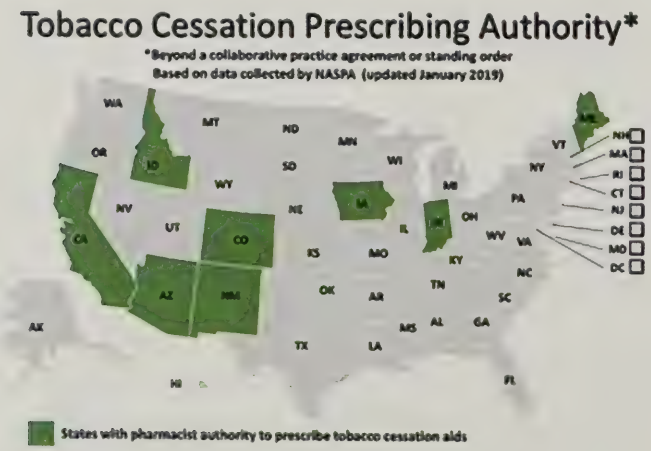
Maryland's Bill

Maryland Senate Bill 497 adds "prescribing and dispensing medications approved by the United States Food and Drug Administration as an aid for the cessation of the use of tobacco products" to the definition of the practice of pharmacy. The legislation calls for the Board of Pharmacy to develop standard procedures that pharmacists are required to use while prescribing tobacco cessation aids. These procedures would include elements such as referral criteria, training, and documentation requirements. The bill goes on to call for the Maryland Children's Health Program to cover tobacco cessation services pharmacists provide to enrollees.

Authority to prescribe tobacco cessation aids is a logical follow up to Maryland pharmacists' authority to prescribe contraceptives and demonstrates to Maryland lawmakers our commitment to ensuring residents have convenient and effective access to important preventive care.

Other States' Experiences

Pharmacists in some other states already can prescribe tobacco cessation aids. Starting with New Mexico back in 2004, eight states have passed legislation to utilize pharmacists to increase access to these important medications. In addition to Maryland, fourteen other states are pursuing similar legislation in the 2019 state legislative sessions.


Tobacco Cessation Prescribing Authority*
*Beyond a collaborative practice agreement or standing order
Based on data collected by NASPA (updated January 2019)
States with pharmacist authority to prescribe tobacco cessation aids

FAQs

What medications would be included in this prescribing authority?

All medications the FDA has approved for use as a tobacco cessation aid.

Would pharmacists be required to have a collaborative practice agreement under this authority?

No. The authority to prescribe under this bill would come from state statute and regulation, without the need for collaborative practice agreements, which often cause barriers to service implementation.

Don't varenicline (Chantix) and bupropion (Zyban) have Black Box Warnings?

No. They used to have Black Box Warnings — but in 2016, after FDA-required post-marketing research, the EAGLES study, FDA removed the warnings due to the strong safety and efficacy profile of these medications. Pharmacists have been safely prescribing all tobacco cessation medications in New Mexico since 2004 — and there have been no problems reported in that time. The study also showed that varenicline provided much higher quit rates compared to nicotine replacement products.

Will pharmacists get paid for prescribing?

No healthcare providers get paid for "prescribing." However, the valuable service associated with prescribing is another story. Research shows that pharmacists are very effective at helping people quit smoking — that's the kind of value that insurers want to cover! With the change in scope Maryland insurance law states that services covered under a policy, contract or certificate, the carrier must reimburse the pharmacist for that service.

Is smoking really a problem in our state anymore?

Yes! 14% of Maryland adults are current smokers and rates are higher in certain areas — with Hagerstown at the top with a 21% smoking rate.

Continuing Ed

Discussion of ACIP Recommendations on Herpes Zoster Vaccination

Diamond Rose Melendez, PharmD Candidate 2019;
Kathleen J Pincus, PharmD, BCPS, BCACP, University of Maryland School of Pharmacy

Learning Objectives

After completing this activity, the pharmacist will be able to:

1. Identify patients who are candidates for Zoster Vaccine Recombinant, Adjuvanted vaccination
2. Describe administration techniques for Zoster Vaccine Recombinant, Adjuvanted vaccine
3. Recognize the mechanism of action of Zoster Vaccine Recombinant, Adjuvanted vaccine
4. Compare the efficacy of Zoster Vaccine Recombinant, Adjuvanted and Zoster Vaccine Live vaccines

After completing this activity, the pharmacy technician will be able to:

1. Identify patients who are candidates for Zoster Vaccine Recombinant, Adjuvanted vaccination
2. Recognize the proper storage and stability conditions for Zoster Vaccine Recombinant, Adjuvanted vaccine

Kewords

- Vaccination
- Zoster
- Shingles

Introduction/Background

Shingles (herpes zoster) is a disease caused by the endogenous reactivation of latent varicella zoster virus, the same virus that causes varicella (chickenpox). The virus can remain dormant in the body for years, and sometimes indefinitely, after a person has recovered from the symptoms of the initial chickenpox infection. As one ages, or becomes immunocompromised, the inactive virus can become reactivated causing shingles.[1–7]

Shingles most commonly presents as a painful rash, usually unilateral, on the face or trunk of the body. As the disease progresses, the rash begins to blister and scab. The rash usually resolves within 2 to 4 weeks. The rash is often preceded by itching, pain, or tingling in the area.[1–4,6] The neuropathic pain experienced is due to viral replication at the nerve cell level. The most active replication site of the virus occurs at the skin and mucous membranes which is mechanistically responsible for the rash.[3] Postherpetic neuralgia (PHN), severe neuropathic pain at the site of the rash, can last for months after initial development of shingles. PHN has a significant impact on quality of life and can be debilitating.[3,5,7] Other symptoms that can occur are fever, headache, chills, and upset stomach.[1,6] The rash can also affect the eye (herpes zoster ophthalmicus) and cause loss of vision.[3,4]

An estimated one million new cases of shingles occur in the United States per year.[1,5,6,8] Thirty-percent of individuals will experience shingles during their lifetime.[8] Any person previously infected with chickenpox is at risk for developing shingles, even if they did not have symptoms of the infection. Those at a higher risk for developing shingles are individuals over 50 years of age and immunocompromised individuals, including those with human immunodeficiency virus (HIV), certain cancers such as leukemia and lymphoma, and people taking immunosuppressive medications. These conditions affect cell-mediated immunity, interrupting the body's defense mechanisms and increasing the risk of shingles development.[4,6,7] Cell-mediated immunity also wanes as a result of aging, a phenomenon called 'immunosenescence'. So it is not surprising that the incidence of shingles increases with increasing age from four cases per 1000 US population annually to ten cases per 1000 US population over 60 years of age.[2] Women have shown an increased incidence of shingles in many studies, though this finding is not universal.[5,7–9]

Herpes zoster can be treated with several antiviral medications including acyclovir, valacyclovir, and famciclovir. If used as soon as possible after the rash appears, the antivirals can shorten the length and severity of illness. Analgesics, wet

compresses, calamine lotion, and colloidal oatmeal baths may help relieve pain and itching associated with the disease.[1,4,6] However, pain from the initial rash and subsequent PHN can be difficult to control with available modalities. Therefore, preventing development of shingles with the use of vaccines is preferred to treatment of the condition once it develops.

ZOSTAVAX

In 2006, Zoster Vaccine Live (Zostavax, ZVL) was approved in the US for prevention of herpes zoster. ZVL is a live attenuated virus vaccine originally indicated for individuals 60 years of age and older. In March 2011, the Food and Drug administration (FDA) approved an extended age range for the use of ZVL to include adults aged 50 to 59 years of age. The following month, the Center for Disease Control (CDC) Advisory Committee on Immunization Practices (ACIP) declined to update their recommendation to reflect this change and instead reaffirmed the recommendation of routine vaccination for individuals 60 years or older.[9,10] ZVL is a lyophilized vaccine that must be reconstituted with supplied diluent. ZVL is administered subcutaneously as a single dose in the fatty layer of tissue under the skin of the arm and should be stored in the freezer until used.[11]

ZVL is contraindicated in individuals with a history of hypersensitivity reaction to gelatin, neomycin, or any other component of the vaccine. The vaccine should not be administered to individuals who are immunodeficient or immunosuppressed as the live vaccine can cause serious or fatal disseminated vaccine strain varicella-zoster virus disease. The vaccine is also contraindicated for use in pregnant women because the varicella-zoster virus can cause congenital varicella syndrome if acquired during pregnancy.[11]

The Shingles Prevention Study (SPS) to Prevent Herpes Zoster and Postherpetic Neuralgia in Older Adults, published in 2005, was a randomized, double-blind, placebo-controlled clinical trial designed to test a hypothesis that herpes zoster vaccine can decrease the incidence and severity of herpes zoster and PHN. A total of 38,546 adults age 60 or older were enrolled in the study and followed for approximately 3 years. Shingles was diagnosed using clinical and laboratory criteria. ZVL significantly reduced the incidence of shingles by 51.3% ($P<0.001$). Vaccine efficacy of ZVL was 37.6% in subjects 70 years and older, and 63.9% in subjects 69 years old and younger. The burden of illness due to herpes zoster was reduced by 61.1% ($P<0.001$), and the incidence of PHN was reduced by 66.5% ($P<0.001$).[12,13]

The Zostavax Efficacy and Safety Trial (ZEST), published in 2012, was designed to determine efficacy, safety, and tolerability of the ZVL for prevention of shingles in subjects aged 50 to 59 years. The ZEST study was a randomized, double-blind, placebo-controlled clinical trial consisting of 22,439 subjects. The subjects were followed for one year after receiving either vaccine or placebo, to monitor for occurrence of herpes zoster. Zoster cases were confirmed by a polymerase chain reaction (PCR) assay for varicella zoster virus DNA from lesion swabs. The vaccine was 69.8% (95% CI: 54.1, 80.6%) effective for preventing herpes zoster.[13,14]

Both the ZEST and SPS studies reported higher adverse events in the treatment group compared to adverse events reported in the placebo groups. The major reported adverse effects were headache and injection site reactions including erythema, pain or tenderness, swelling, pruritus, warmth, hematoma, and rash. SPS participants who received ZVL experienced higher incidence of injection site reactions and headaches in comparison to placebo (injection site reaction: 48% ZVL and 17% placebo, headache: 1.4% ZVL and 0.8% placebo). The overall incidence for injection site reaction and headaches was also greater for patients who received ZVL versus placebo in the ZEST trial (injection site reaction: 63.3% ZVL and 14.0% placebo, headaches: 9.4% ZVL and 8.2% placebo).[12–14]

There is data suggestive that ZVL effects wane over time, decreasing protection against herpes zoster within the first five years. The protection from the vaccine beyond five years is uncertain, and the need for revaccination is not yet clear. Therefore, adults who receive the vaccine before 60 years of age may not be protected during later years, when at the highest risk for developing herpes zoster.[15,16]

The ZVL package insert advises consideration of spacing ZVL at least 4 weeks apart Pneumococcal Vaccine Polyvalent (Pneumovax 23) based on data suggesting a reduced immune response to ZVL when the vaccines were administered concomitantly.11 However the ACIP has not changed the recommendations on simultaneous administration. The ZVL also notes that antiviral medications with activity against zoster have not been studied with ZVL.11 No other major drug interactions are noted.

SHINGRIX

Zoster Vaccine Recombinant, Adjuvanted (Shingrix, RZV) is a newer vaccine for the prevention of herpes zoster, approved by the FDA on October 20, 2017.[17] The

Active Learning — Patient Case

Franklin Smith is a 55 year-old patient who presents to your community pharmacy to pick up his monthly refills of metformin, lisinopril, and hydrochlorothiazide. He is an overall healthy man, born in Baltimore Maryland, with no known drug allergies and a past medical history significant for hypertension and type 2 diabetes mellitus. In addition to his prescription medications, he takes a Men's One-A-Day vitamin and low-dose aspirin daily, which he purchases over the counter. Mr. Smith tells you that he heard of a new shingles vaccine on the radio and has some questions.

1. Which vaccination should you recommend to Mr. Smith today to prevent shingles?

a. Shingrix
b. Zostavax
c. Pneumovax 23
d. Varicella

2. Mr. Smith is uncertain about his prior history of chickenpox. Should he be considered for Shingrix vaccination?

a. Yes, as he most likely had chickenpox as a child
b. No, as he has never had chicken pox
c. No, as he most likely received the varicella vaccine as a child
d. Both B and C are correct

3. Mr. Smith's wife is also with him today. She is 65 years-old and received Zostavax when she was 60 years old. Which of the following statements is correct?

a. Another dose of Zostavax should be administered to Mrs. Smith today
b. Since Zostavax was administered, there is no need to administer Shingrix.
c. Since a dose of Zostavax was received, only one dose of Shingrix is recommended.
d. Two doses of Shingrix vaccine are still recommended for patients who have previously received Zostavax.

4. Mr. Smith agrees to receive a dose of the Shingrix vaccine today. Which of the follow statements is true?

a. The patient should return in one month to receive a second dose of Shingrix
b. The patient should return in two months to receive a dose of Zostavax
c. The patient should return in two months to receive a second dose of Shingrix
d. An additional dose of Shingrix is not needed for shingles prevention

5. Which of the following is the most common side effect after receiving Shingrix?

a. Headache
b. Sneezing
c. Injection Site Reaction
d. Tinnitus

Answers on page 18

ACIP added a recommendation to administer RZV for all immunocompetent adults aged 50 years or older on October 25, 2017.[17] The vaccine is not indicated for prevention of varicella infection. RZV is a recombinant, adjuvant vaccine that boosts varicella zoster virus (VZV)-specific immune response. This boost in VZV-specific immune response offers protection against zoster disease to those with age-related decline in VZV-specific immunity. RZV is contraindicated in anyone with an allergy or history of anaphylaxis to any component of the vaccine.[18]

RZV is a sterile suspension for intramuscular injection only.

The vaccine is supplied as a vial containing lyophilized recombinant varicella zoster virus surface glycoprotein E (gE) antigen component. The contents of the vial must be reconstituted at the time of use with an additional vial provided containing AS01 adjuvant suspension component. The lyophilized gE antigen component is a sterile white powder and the AS01 adjuvant component is a colorless to pale brownish liquid. After reconstitution the product should be an opalescent, colorless to pale brownish liquid.[18]

Before reconstitution, both vials associated with the vaccine should be stored in the refrigerator at 2°C to 8°C (36 and 46 °F). Do not freeze any components of the vaccine. If any component of the vaccine is frozen, it should be discarded. Vials should also be protected from light. Reconstituted RZV can be stored in the refrigerator for up to 6 hours, after which the vaccine should be discarded.[18]

To reconstitute the vaccine, use a sterile needle and syringe to withdraw the entire contents of the vial containing the adjuvant suspension component. Transfer the contents of the syringe into the second vial containing lyophilized gE antigen. Gently shake the vial until contents are dissolved and mixed completely. The FDA RZV

package insert contains detailed instructions of reconstitution along with an accompanying figure. After reconstitution, a single dose of 0.5 mL should be administered in the deltoid region of the upper arm. The vaccine is a 2-dose series. After the first dose of RZV is administered, a second dose should be given 2 to 6 months later.[18]

Two placebo-controlled clinical studies were conducted to assess the safety and efficacy of RZV. The first study, Efficacy of an Adjuvanted Herpes Zoster Subunit Vaccine in Older Adults (ZOE-50), published in 2015, was a phase 3 trial conducted in 18 countries consisting of 15,411 adults 50 years of age or older. Randomization was stratified by age (50 to 59, 60 to 69, and ≥70 years). Each participant received two doses of RZV or placebo two months apart and were followed for 3.2 years to monitor for herpes zoster and adverse events. The treated group consisted of 7,698 participants and the placebo group contained 7,713 participants. During the 3.2 year follow-up, 6 participants in the treated group had confirmed herpes zoster compared to 210 confirmed cases in the placebo group. Overall vaccine efficacy against herpes zoster was 97.2% (CI: 93.7 to 99.0; P<0.001). For all groups, vaccine efficacy was between 96.6% and 97.9%, with no significant difference in vaccine efficacy among the age groups. The RVZ vaccine significantly reduced the risk of herpes zoster in adults 50 years of age or older.[19]

The second study, Efficacy of the Herpes Zoster Subunit Vaccine in Adults 70 Years of Age or Older (ZOE-70), published in 2016, was also a phase 3 trial conducted in 18 countries that involved adults 70 years of age or older. Participants received two doses of RZV or placebo two months apart and were followed for an average of 3.7 years. A total of 13,900 adults were evaluated, with 6,950 participants receiving RVZ and 6,950 participants receiving placebo. Shingles occurrence was determined in 23 RVZ recipients and 223 placebo recipients. Vaccine efficacy against shingles was 89.8% (95% CI, 84.2 to 93.7; P<0.001). Pooled analysis of adults 70 years or older from both ZOE-50 and ZOE-70 trials yielded a vaccine efficacy against herpes zoster of 91.3% and vaccine efficacy against PHN of 88.8%.[20]

Commonly reported solicited symptoms were injection-site reactions and systemic reactions. Of ZOE-50 participants, 81.5% of RVZ recipients experienced injection site reactions and 66.1% experienced systemic reactions. Of ZOE-70 participants, 74.1% of RVZ recipients experienced injection site reactions and 53.0% experienced systemic reactions. The most common injection site reaction was pain and the most common systemic reactions were fatigue and myalgia. Adverse events lasted a median of 2 to 3 days for local adverse reactions and general adverse events of pain, redness, swelling, myalgia, fatigue, headache, shivering, fever and gastrointestinal symptoms.[19,20]

Reported adverse events that occurred in at least 1% of recipients and at a rate at least 1.5-fold higher than placebo included: chills, injection site pruritus, malaise, arthralgia, nausea, and dizziness. Gout was reported in 27 vaccine recipients (0.18%) compared to 8 cases (0.05%) of placebo recipients; however, causal relationship with RVZ cannot be determined.[18–20]

According to both clinical studies ZOE-50 and ZOE-70, overall incidence of serious adverse events and potential immune-mediated diseases were similar in both study groups. Serious adverse events were reported in 10.1% of vaccine group and 10.4% of placebo group. One case of lymphadenitis and one case of fever greater than 39°C was reported and determined to have a basis for a causal relationship to RVZ. Three cases of optic ischemic neuropathy were reported in participants who received the vaccine; however, causal relationship with RVZ cannot be determined.[18–20]

There are very few drug interactions reported with RZV. Immunosuppressive therapies may reduce the effectiveness of the vaccine. Concomitant administration of inactivated influenza vaccine does not interfere with the immune response to any antigens of either vaccine.[18]

Special Populations

Special populations to consider with regards to any vaccination are pregnancy, children, and immunocompromised patients. As ZVL is a live vaccine, it is contraindicated in pregnant women and it is recommended that pregnancy be avoided for 3 months following vaccination.[11] While RZV is a recombinant vaccine, there are no available human data to establish vaccine-associated risk of RZV in pregnant women. In a toxicity study performed in female rats, there was no adverse effects on fetal or pre-weaning development due to RZV.18 There are no available data regarding whether either ZVL or RVZ are excreted in human milk, nor is there data available to assess the effects of

either vaccine product on infants who are breastfeeding.[11,18] Neither ZVL or RZV are indicated for primary prevention of varicella infection, and are not indicated for children 18 years or younger.[11,18] ZVL is contraindicated in patients with immunodeficiency or immunosuppression.[11] Decreased immune function is not listed as an explicit contraindication for RZV, though such patients were excluded from published studies with the product. It is noted in the RZV package insert that immunosuppressive therapies may decrease effectiveness. As RVZ is not a live vaccine, there may be less risks associated with administration of the vaccine in immunocompromised patients compared to a live attenuated vaccine, but further investigation is needed before recommendations can be made in this population.

Comparison of Available Vaccines[11,17,18]

	ZOSTAVAX (ZVL)	SHINGRIX (RZV)
Efficacy	Shingles prevention in 50-59 y/o 69.8% Shingles prevention in ≥60 y/o 51.3%	Shingles prevention in ≥50 y/o 97.2% Shingles prevention in ≥70 y/o 89.8%
Adverse Drug Events, Common	Injection site reaction Headache	Injection site reaction Myalgia Fatigue
Age of recommendation (ACIP)	≥60 y/o	≥50 y/o
Type of vaccine	Live attenuated virus vaccine	Subunit recombinant, adjuvanted vaccine
Dosage Schedule	1-dose (0.65mL)	2-dose series (0.5mL each)
Route of administration	Subcutaneous	Intramuscular
Storage	Frozen (-50°C to -15°C)	Refrigerated (2°C to 8°C)

ACIP recommendations state that RZV should be used in immunocompetent adults aged 50 years or older. ACIP recommendations continue to include ZVL as a vaccine for prevention of herpes zoster in immunocompetent adults aged 60 or older. A majority of ACIP members voted that the RZV was preferred, as is reflected in the current recommendation. RZV has been estimated to prevent more cases of herpes zoster and PHN when compared to ZVL. However, there are no clinical studies that directly compare both vaccines.[17]

In 2018, a cost-effective analysis comparing ZVL to RZV was published. Since RZV requires a two-dose series, even with equivalent coverage this will be more costly to both the patient and the health-care system. However, the analysis found that under most assumptions, RZV vaccination prevented more cases of herpes zoster at a lower overall cost than ZVL vaccination.[17] Curran and colleagues also conducted a cost effectiveness analysis that showed RZV to be cost effective compared to no vaccination and cost-saving compared to ZVL.[21]

Per the ACIP recommendations, adults who previously received ZVL will likely benefit from receiving RZV. This is based on efficacy data from separate clinical trials and not head-to-head comparisons. But, studies show protection from ZVL wanes over time, and the greatest differences in efficacy are seen in patients age 70 years or older. Age and time since ZVL vaccination may be considered when recommending RZV to someone previously vaccinated with ZVL. Studies have investigated the safety and immunogenicity of administration of RZV five years after receiving ZVL compared to no prior ZVL vaccination and shown similar safety, reactogenicity, and immunogenicity profiles.[17] The CDC morbidity and mortality weekly report (MMWR) states adults 50 years and older should receive RZV irrespective of prior receipt of varicella vaccine or ZVL.[2,17]

Pharmacist Responsibilities in Patient Counseling

As pharmacists, we must stress the importance of vaccination. It is important to screen for patients who are eligible to receive vaccination to prevent shingles according to the current ACIP recommendation. Zoster vaccines are covered under Medicare Part D, therefore many patients with this coverage may seek vaccination at pharmacies instead of physician offices. Pharmacists can discuss the current ACIP recommendations and differences between zoster vaccine products with patients. Patients should be educated that those who previously received ZVL are still recommended to receive the 2-dose series of RZV.[2,17] Patients commonly ask if they need vaccination against zoster if they have never had chickenpox. The

answer is yes. Many patients in this age group had a varicella infection but may not remember or may not have presented with skin eruptions. According to the CDC, 99.5% of people over 40 years old have been infected with varicella zoster virus.[2] A person who received the varicella vaccine and never had chickenpox should also be vaccinated against herpes zoster, though few people currently approaching 50 years of age received the varicella vaccine since vaccination began in 1995. If a patient is known to be VZV seronegative they are not indicated for vaccination, though uncertainty of prior varicella infection is not an indication for testing.

Pharmacists should inform patients of the importance of completing the 2-dose immunization series on schedule if the RZV product is selected. Be proactive and schedule the second dose of RZV with your patients in 2 to 6 months to increase vaccination completion compliance. Pharmacists can discuss that ZVL is an alternative option for patients over 60 years old. ZVL may be the most appropriate option for patients with allergies to RZV, when RZV is unavailable, and based on patient preference. Inform patients about potential adverse reactions and emphasize that adverse reactions are temporary, usually lasting 2–3 days. Discuss common side effects such as pain, redness, swelling, myalgia, fatigue, headache, shivering, and fever. Inform patients of hypersensitivity reaction symptoms and when to seek medical attention. Pharmacists should discuss the potential benefits and risks of immunization against zoster with patients 50 years or older.

Summary

Herpes Zoster is a painful disease that can be prevented with vaccination. Two vaccine products are available to prevent herpes zoster and postherpetic neuralgia. RZV is the newest product, and is preferentially recommended by the ACIP. Patients and community members may be confused by the new recommendations and availability of multiple vaccine products. Individuals who are immunocompetent and 50 years of age or older should be advised

ANSWERS | Active Learning — Patient Case

1 Answer: A. Both Shingrix and Zostavax are approved for prevention of shingles. Mr. Smith is under 60 years of age and Shingrix is the preferred agent for this age group. [Answer A is correct, Answer B is incorrect]. Mr. Smith is indicated to receive Pneumovax 23 given his diagnosis of diabetes mellitus. But this is a pneumococcal vaccine, and will not prevent shingles [Answer C is incorrect]. Varicella vaccine protects against chickenpox however, is not indicated for shingles prevention [Answer D is incorrect]. Since Mr. Smith was born before 1980, he is considered to have evidence of immunity to varicella.

2 Answer: A. Varicella vaccination began in 1995 therefore adults over 50 years of age are unlikely to have received the vaccine [Answers C and D are incorrect]. According to the CDC, 99.5% of people over 40 years of age have been infected with varicella zoster virus. Some individuals in this age group may not remember their chickenpox infection, may not have had an official diagnosis, or may not have presented with skin eruptions [Answer B incorrect]. Screening for a history of varicella before vaccination for herpes zoster is not recommended. Therefore Mr. Smith is indicated for Shingrix vaccination [Answer A is correct].

3 Answer: D. Shingrix is recommended for patients who have previously received Zostavax. Studies have shown that immunity wanes over time, decreasing efficacy to prevent shingles. Studies have been conducted administering Shingrix > 5 years after Zostavax and have shown efficacy. [Answer B is incorrect]. A 2-dose series is necessary for complete Shingrix efficacy, regardless of prior Zostavax administration [Answer C is incorrect, Answer D is correct]. Zostavax requires only one dose and a second dose would not be necessary [Answer A is incorrect].

4 Answer: C The Shingrix vaccine is a 2-dose series that should be administered intramuscularly in the deltoid muscle of the arm [Answer D is incorrect]. After the first dose is administered, a second dose should be given in 2 to 6 months [Answer C is correct, Answer A is incorrect]. Since the two vaccines are formulated differently, they are not interchangeable [Answer B is incorrect].

5 Answer: C Injection site reaction (26-78%) is the most commonly reported adverse event followed by myalgia (45%) and fatigue (45%) [Answer C is correct]. Headaches are also a side effect of Shingrix however, they are less common (38%) [Answer A is incorrect]. Tinnitus and sneezing have not been reported after administration of Shingrix [Answer B and D are incorrect].

to consider vaccination with RZV as the benefits outweigh the risk of vaccination in most. ZVL can be considered for immunocompentent patients 60 years of age or older. Pharmacists should screen for patients who are eligible to receive the vaccine and discuss vaccine efficacy, safety, and dosing schedule. If adverse reactions should occur after administration of the vaccine, report the event to Vaccine Adverse Event Reporting System (VAERS).

REFERENCES

1. Centers for Disease Control and Prevention. Shingles. https://www.cdc.gov/shingles/about/overview.html. Updated June 15, 2018. Accessed September 21, 2018.
2. Centers for Disease Control and Prevention. Shingles. https://www.cdc.gov/shingles/hcp/clinical-overview.html. Updated February 21, 2018. Accessed October 1, 2018.
3. Pietro AD, Facciolà A, Visalli G. Herpes zoster vaccine: a protection for the elderly. Ann Ig. 2018;30(4 Suppl 1):23-27. doi:10.7416/ai.2018.2230.
4. Wareham DW, Breuer J. Herpes zoster. BMJ. 2007;334(7605):1211-1215. doi:10.1136/bmj.39206.571042.AE.
5. Insinga RP, Itzler RF, Pellissier JM, Saddier P, Nikas AA. The Incidence of Herpes Zoster in a United States Administrative Database. J Gen Intern Med. 2005;20(8):748-753. doi:10.1111/j.1525-1497.2005.0150.x.
6. National Institutes of Health. Protecting Yourself From Shingles. NIH MedlinePlus the Magazine Website. https://medlineplus.gov/magazine/issues/winter10/articles/winter10pg16-17.html. Accessed September 21, 2018.
7. Johnson RW, Wasner G, Saddier P, Baron R. Herpes zoster and postherpetic neuralgia: optimizing management in the elderly patient. Drugs Aging. 2008;25(12):991-1006. doi:10.2165/0002512-200825120-00002.
8. Shingles. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed September 21, 2018.
9. Harpaz R, Ortega-Sanchez IR, Seward JF. Prevention of herpes zoster recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep. 2008;57(RR-5):1-30.
10. Centers for Disease Control and Prevention. Update on herpes zoster vaccine: licensure for persons aged 50 through 59 years. MMWR Morb Mortal Wkly Rep. 2011;60(44):1528.
11. U.S. Food and Drug Administration. Zostavax. https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm136941.htm. Updated September 27, 2018. Accessed October 14, 2018.
12. Oxman MN, Levin MJ, Johnson GR, et al. A vaccine to prevent herpes zoster and postherpetic neuralgia in older adults. N Engl J Med. 2005;352(22):2271-2284. doi:10.1056/NEJMoa051016.
13. Keating GM. Shingles (Herpes Zoster) Vaccine (Zostavax®): A review of its use in the prevention of herpes zoster and postherpetic neuralgia in adults aged ≥50 years. Drugs. 2013;73(11):1227-1244. doi:10.1007/s40265-013-0088-1.
14. Schmader KE, Levin MJ, Gnann JW Jr, et al. Efficacy, safety, and tolerability of herpes zoster vaccine in persons aged 50–59 years. Clin Infect Dis. 2012;54(7):922-928. doi:10.1093/cid/cir970.
15. Schmader KE, Oxman MN, Levin MJ, et al. Persistence of the efficacy of zoster vaccine in the shingles prevention study and the short-term persistence substudy. Clin Infect Dis. 2012;55(10):1320-1328. doi:10.1093/cid/cis638.
16. Hales CM, Harpaz R, Ortega-Sanchez I, Bialek SR. Update on recommendations for use of herpes zoster vaccine. MMWR Morb Mortal Wkly Rep. 2014;62(33):729-731.
17. Dooling KL, Guo A, Patel M, et al. Recommendations of the Advisory Committee on Immunization Practices for use of herpes zoster vaccines. MMWR Morb Mortal Wkly Rep. 2018;67(3):103-108. doi:10.15585/mmwr.mm6703a5.
18. U.S. Food and Drug Administration. Shingrix. https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm581491.htm. Updated September 19, 2018. Accessed October 14, 2018.
19. Lal H, Cunningham AL, Godeaux O, et al. Efficacy of an adjuvanted herpes zoster subunit vaccine in older adults. N Engl J Med. 2015;372(22):2087-2096. doi:10.1056/NEJMoa1501184.
20. Cunningham AL, Lal H, Kovac M, et al. Efficacy of the herpes zoster subunit vaccine in adults 70 years of age or older. N Engl J Med. 2016;375(11):1019-32. doi:10.1056/NEJMoa1603800.
21. Curran D, Patterson B, Vargehese L, et al. Cost-effectiveness of an adjuvanted recombinant zoster vaccine in older adults in the United States. Vaccine. 2018;36(33):5037-5045. doi:10.1016/j.vaccine.2018.07.005.

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Adv

Legislative Priorities

As this issue goes to press, the bills are in legislative drafting and have not received bill numbers. We look forward to activating our grassroots network and collaborating with the Maryland Pharmacy Coalition and other healthcare providers in support of these legislative initiatives.

Please look for future communications about this legislation.

Prescriptive Authority for Tobacco Cessation Medication

- A pharmacist may prescribe and dispense tobacco cessation aids approved by the U.S. Food and Drug Administration
- Regulations to be established by the Maryland Board of Pharmacy to establish standard procedures a pharmacist should follow to: prescribe and dispense the appropriate tobacco cessation aid; and refer the patient to a primary care practitioner for treatment
- Continuing education requirement; training waived for a pharmacist who already has undergone the training as part of the pharmacist's formal educational program
- A pharmacist will notify the patient's primary care provider (if the patient does not have a primary care provider, the pharmacist can refer the patient to a primary care practitioner) or record the prescribing and dispensing of the tobacco cessation aids in any electronic health record maintained for the patient
- Plans/payors may not impose a different copayment or coinsurance requirement for a drug or nicotine replacement therapy provided by the pharmacist.

Pharmacist Administration of Injectable Medications

- Add pharmacist administration of injectable medications and biological products to the self-administered medications statute
- Board of Pharmacy to develop regulations in consultation with Board of Physicians and Board of Nursing
- Training on patient management of disease state, waived if part of formal education program
- Provide patient with written record
- Pharmacist maintains health record with pertinent details about the patients' condition
- Medication adherence notification to prescriber
- Public and private payment for services at the same extent rendered by any other healthcare practitioner

PBM Transparency

- Requires that all Medicaid MCO pharmacy dispensing be reimbursed at the rate equivalent to the Medicaid fee-for-service program (NADAC + dispensing fee)
- This effort is being pursued at the administrative level as well.

E-Prescribing for Controls

- Legislation as introduced requires e-prescribing for all prescriptions
- Provides for some exceptions, and requires regulations regarding waivers to be adopted by the Maryland Health Care Commission
- Violations are subject to a fine
- Pharmacist is not required to verify if a written or oral prescription is an authorized exception to the e-prescription requirement

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Executive Director's Message

I enjoy staying up-to-date on the latest thoughts on leadership, organizational management and health and wellness. There's so much on mindfulness, strategy and collaboration. At the start of each new year, I use that information to make resolutions for personal and professional improvements. Yet, despite the importance these changes would have, like most people, many of my resolutions go astray before the end of the first quarter! As the meetings pick up and the work days are longer, I'm already starting to feel challenged on a few. *I need some support on having fruit salad instead of cookies at the MPhA meetings!*

As I reflect on MPhA, it is clear we do not have the luxury of letting our resolve lapse — there's too much at stake. We are committed to supporting patients achieving better health outcomes via access to and engagement with pharmacists. That means we must ensure that community pharmacies are around to serve all who need them. We must continue to provide education that shares new and best practices; support training that maintains the ability to practice at the height of pharmacist and pharmacy technician licensure; ensure that legislation and regulations enhance and do not detract from pharmacy practice and professional abilities to serve; and provide networking and leadership opportunities to facilitate career development.

Under the leadership of the Board of Trustees and support of committed volunteers, we are doing just that. The MPhA Foundation is reinvigorated and is working with MPhA to remain resolute in our efforts.

MPhA's vision is to be the voice representing all Maryland pharmacists as innovative and respected members of the healthcare team focused on the health and well-being of Maryland residents.

We need you and your colleagues to ensure that Maryland is a great place to practice and the profession continues to serve the greater good!

Let's do this!

The best work we can all do is create the highest vision possible... and be led by that vision to the greatest good.

– Oprah Winfrey

Aliyah N. Horton, CAE
Executive Director

First Quarter 2019: Pharmacy Time Capsule

By: Dennis B. Worthen, PhD, Cincinnati, OH

1994

- The first organized movement to train pharmacists to provide immunizations began in Washington state

1969

- Fentanyl marketed by McNeil in US
- Clinical pharmacy defined as dealing with patient care with emphasis on drug therapy
- Martin Luther King murdered in Memphis

1944

- Most of American life was focused on the progress of WW II in Europe and the Pacific
- D-Day June 6, 1944
- The United States Forest Service and the Wartime Advertising Council release posters featuring Smokey Bear for the first time

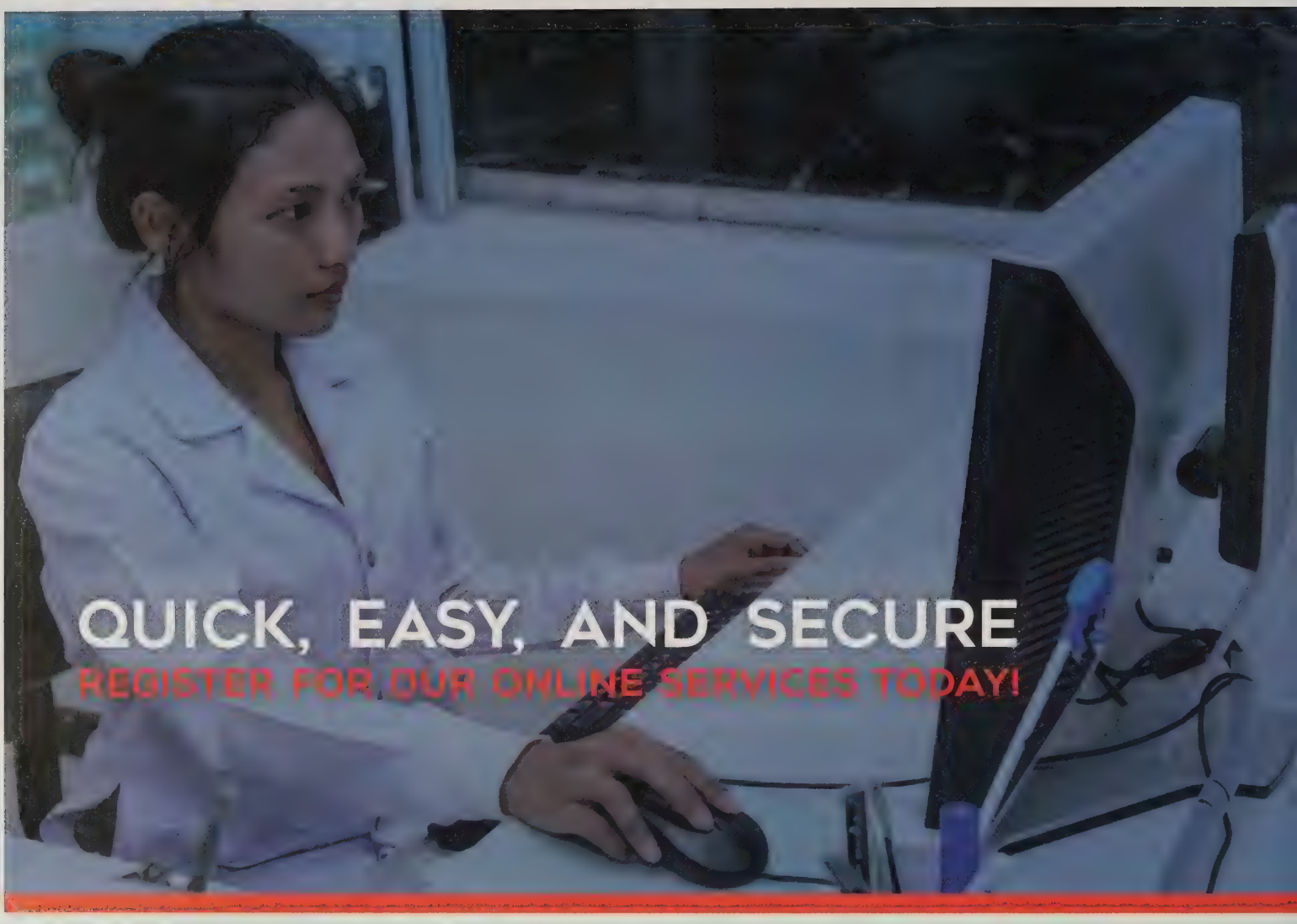
1919

- Webb et al v. United States court case confirms that physicians and pharmacists cannot supply an addict just to maintain his or her addiction

1894

- Formation of the University of Washington College of Pharmacy
- The first bottles of Coca-Cola were sold in Vicksburg, Mississippi

One of a series contributed by the American Institute of the History of Pharmacy, a unique non-profit society dedicated to assuring that the contributions of your profession endure as a part of America's history. Membership offers the satisfaction of helping continue this work on behalf of pharmacy, and brings five or more historical publications to your door each year. To learn more, check out: ***www.aihp.org***



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Updates: CHEST Guideline 10th Edition, 2018 Antithrombotic Therapy for Atrial Fibrillation

MPhA 137th Annual Convention

Advocacy
Changes in Maryland PDMP Dispenser Reporting Requirements

Continuing Education
Pharmacist Prescribing of Contraception in Maryland

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Rich Pinckney, R.Ph., Owner
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June 21-24, 2019 • Ocean City, MD

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President's Pad

Dear MPhA Members,

As I reflect upon my year serving as your president, I find myself excited about the future of the association. The hard work and dedication of our staff, member volunteers, committee leads, trustees, and past presidents have established an infrastructure that will serve as the foundation to increase membership value, community engagement, and flexibility to respond to organizational priorities. The spirit of imagineering, our willingness to transform the association through innovation, has created new possibilities for professional development and social events, membership involvement, and even our signature Midyear and Annual meetings.

I am encouraged to see that in the past year, more members are participating in the opportunities offered by the association. It is a good sign that suggests the foundation built by the committees this year will stimulate future growth through newly expanded offerings. From webinars on clinical and professional topics to a visit to the APhA archives, members choose from an array of programming to find value in different ways, reflecting your diverse interests. The association has also started the process of revitalizing its relationships with our federal pharmacists, technicians, and new practitioner members through our various networks. With frequent collaboration among committees as well as the MPhA Foundation, the networks are continuously looking to engage new members and get them involved.

It has been a privilege to serve all of you over the past year; thank you for trusting me with your association and allowing me the opportunity to help shape its future. I look forward to seeing many of you at our annual meeting in Ocean City!

Looking toward the future, I believe that the transition taking place at our June Annual Convention in Ocean City is the next phase in the association's growth. The infrastructure and events developed this year can be refined as the association continues to respond to your input as engaged members. I encourage all of you to bring new perspectives to our committees next year and continue the momentum forward. It is with your support that MPhA accomplishes what it sets out to do, from advocating for our members through new legislation in Annapolis to obtaining grants to support community initiatives on preventing opioid drug abuse. Your voices are important: please continue participating and sharing your thoughts and ideas with us.

As the year draws to a close, I would be remiss if I did not take a moment to thank the association staff, trustees, committee chairs, and past presidents who have supported my vision. This year, each committee received multiple

charges to establish infrastructure, create membership value, and evaluate future growth opportunities. Past presidents and trustees provided historical perspective to ensure each process and event was carefully planned. Our valued MPhA staff set up and supported the association to ensure smooth and professional operations. Because of everyone's dedication, we were able to achieve many of the goals set forth this year. Finally, I would like to thank my wife Deanna and daughter Cassie for their patience and support; they have helped to keep me grounded during this whirlwind year of change and growth.

It has been a privilege to serve all of you over the past year; thank you for trusting me with your association and allowing me the opportunity to help shape its future. I look forward to seeing many of you at our annual meeting in Ocean City!

With gratitude,

Chai Wang, PharmD, BCPS, AE-C
President, Maryland Pharmacists Association 2018-2019

MPhA *Welcomes* OUR NEWEST MEMBERS

Welcome to MPhA, we are happy to have you! If you meet these new members, please welcome them to the MPhA pharmily. Be sure to invite them to join a committee or attend a networking event!

Pharmacist

Raghda Albarrak (Bowie)

Trudy Merl (Gwynn)

Erin South (Dunkirk)

Megan Sadoughi (Ellicott City)

Anne Marie Sherwood (Derwood)

Katherine Suskevich (Middle River)

Erin Van Meter (Rockville)

Blessing Ekamki (Owings Mills)

Technician

Rachel Harvey (Frederick)

Student

Mbinze Nzuonkwelle (Husson University)

Idovic Azafack Tsague (University of Maryland Eastern Shore)

Russell Arceo (Roseman University)

Binita Bhusai (University of Maryland Baltimore)

Haeyoung Choi (Virginia Commonwealth University)

Relindis Mbah (Lake Erie College)

Souraya El-Sayed Abdallah (University of Illinois)

Out of State

Frederick Frimpong (TX)

Elizabeth Yuan (NJ)

SAVE THE DATES IN YOUR 2019 CALENDAR

May 30
Membership Committee Meeting

Jun 1
MPJE Review

Jun 21-24
137th Annual Convention

For more information and additional activities, visit www.marylandpharmacist.org.

Member Mentions & News You Can Use

In Memoriam — Alfred Abramson

Longtime friend and colleague Alfred "Fred" Abramson, passed away on March 2. Fred left a distinguished legacy in Maryland as pharmacist, education and mentor. His intellect, charm and care for others was revered in the pharmacy community as well as the halls of the University of Maryland School of Pharmacy (UMB) where he taught for decades a in the Department of Pharmacy Practice and Science, in what was affectionately named "Fred Lab." He was also known for his 10 "Rules of Success," which were posted in Fred Lab and some of which included, "It's not a sin to make money;" "Don't take anything personally," "Talk slowly but think quickly;" "Be the first to forgive;" "Share your knowledge. It's a way to achieve immortality;" and "Never swap your integrity for money, power, or fame." He was the past recipient of MPhA's Seidman Distinguished Achievement Award (2012), MPhA Mentor Award (2005) and served as Honorary President (1998).

MPhA at APhA

It was great to see so many Maryland pharmacists, students, and technicians in Seattle at the APhA Annual Meeting!

Special thank you to the hardworking MPhA members representing Maryland in the APhA2019 House of Delegates — thank you for your service!

And we had fun celebrating with all of you at the Maryland Pharmacy Night! Thank you to Notre Dame of Maryland University School of Pharmacy, University of Maryland School of Pharmacy and the University of Maryland Eastern Shore School of Pharmacy, for once again co-hosting this fun event!

Congratulations to the MPhA members who received recognition during the meeting:

- Joey Mattingly — Albert B. Prescott Pharmacy Leadership Award
- Deanna Tran — APhA-ASP Advisor of the year
- Cynthia Boyle — APhA Foundation Jake Miller Award
- Amy Howard — APhA Foundation Scholarship
- Cherokee Layson-Wolf — Honorable Mention for APhA Immunization Champion

MPhA Receives Funding Support for Outreach and Education

MPhA received funding to support pharmacies role in reducing opioid deaths in Maryland. The grant supports outreach and education on the state's Naloxone Standing Order and to encourage dispensing of naloxone within Howard County. MPhA is engaged in delivering resources, marketing materials and webinars targeted toward community pharmacy staff in Howard County.

MPhA also received funding support to develop grassroots outreach and education about the role of Pharmacy Benefit Managers in the pharmaceutical pipeline and their impact on community pharmacy. The grant supported digital media outreach, radio and print advertisements. You may have seen the full-page ad in the Baltimore Sun or heard the radio spots on WBAL, WTOP and NPR.

MPhA Tours APhA Archives

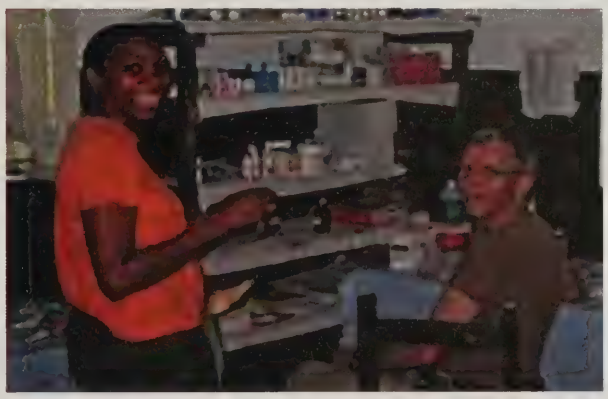
Thank you to the American Pharmacists Association and the APhA Foundation for hosting us this past April for an APhA Archives Tour! Members from MPhA and the Washington DC Pharmacy Association toured artifacts, paintings depicting pharmacy history, and had a blast! And thank you to the MPhA Heritage Committee for sponsoring this event! More photos from the tour can be found on our Facebook page.

MPhA Foundation Hosts Successful 1st Annual Soup-erb Contest!

Thank you to everyone who made the 1st Annual Soup-erb Contest, benefiting the MPhA Foundation, such a hit! And congratulations to our contest winner, MPhA Board of Trustees Member Sam Houmes, PharmD, BCACP, and all of the pharmacies who entered the contest! Additional photos from the night can be found on our Facebook page.

Member Spotlight: Frank Nice

Pharmacist and MPhA member, Dr. Frank J. Nice founded the Medical Mission to Haiti, in 1995. He has organized over 70 medical missions and has personally traveled to Haiti 24 times. Dr. Nice has recruited and supported over 1,000 health-care and lay medical mission volunteers. Among those volunteers are Marylanders from the University of Maryland Eastern Shore School of Pharmacy, the Johns Hopkins School of Nurse Practitioners, and numerous other organizations. As part of his service to Haiti, Dr. Nice founded, built and continues to support a school and orphanage for 550 Haitian children in Leon, Haiti.



MPhA
2019 MID-YEAR MEETING
FEBRUARY 10 · HYATTSVILLE

MPhA 2019 Mid-Year Meeting

Sunday, February 10, 2019

Thank you to all who attended the MPhA 2019 Mid-Year Meeting!
We had great attendance, excellent educational sessions, and perfect weather!

And a special thank you to our generous sponsors and exhibitors.

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Dennis McAllister
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Cissy Clark
Arkansas

Debby Johnson
California

Catherine Jarvis
Colorado

Marghie Giuliano
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Georgia

Starlin Haydon-Greatting
Illinois

Bernadette Brown
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Mickey Cooper
Iowa

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Kansas

Pat Mattingly
Kentucky

Nick LeBas
Louisiana

Betty J. Harris
Maine

Dixie Leikach
Maryland

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Rhode Island

Robert Hubbard
South Carolina

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South Dakota

Larry Calhoun
Tennessee

Carol Reagan
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Darryl Wagner
Utah

Allen Huffman
Virginia

Linda Garrelts MacLean
Washington

Ivan Cephas
Washington DC

Charles "Laddie"
Burdette, Jr.
West Virginia

Brook DesRivieres
Wisconsin

Stephen Rogers
Wyoming

The Bowl of Hygeia award program was originally developed by the A. H. Robins Company to recognize pharmacists across the nation for outstanding service to their communities. Selected through their respective professional pharmacy associations, each of these dedicated individuals has made uniquely personal contributions to a strong, healthy community. We offer our congratulations and thanks for their high example. The American Pharmacists Association Foundation, the National Alliance of State Pharmacy Associations and the state pharmacy associations have assumed responsibility for continuing this prestigious recognition program. All former recipients are encouraged to maintain their linkage to the Bowl of Hygeia by emailing current contact information to awards@naspa.us. The Bowl of Hygeia is on display in the APhA History Hall located in Washington, DC.

Boehringer Ingelheim is proud to be the Premier Supporter of the Bowl of Hygeia program.

SAVE THE DATE

MPhA 137TH ANNUAL CONVENTION

THE NEW FRONTIER

JUNE 21-24, 2019

CLARION RESORT FONTAINEBLEAU HOTEL · OCEAN CITY, MD

You're invited to attend MPhA's 137th Annual Convention

where pharmacists,pharmacy technicians, and student pharmacists from the surrounding regions convene, learn, network and engage with colleagues and peers! We hope you will come join us for a four-day convention at the beach with ample opportunities to broaden your knowledge in the pharmacy profession.

Highlights include:

- CEs on the most current trends in the pharmacy profession
- Opportunities to network, connect, and re-connect with your peers
- Chances to gain new perspectives from our dynamic speakers
- Recognition of professional accomplishments
- Social activities all ages can enjoy

Hotel Information

The Clarion Resort Fontainebleau is offering discounted hotel rates for MPhA attendees. To reserve your room, call the Clarion directly at 1-800-638-2100. You must tell the reservation agent you are with the Maryland Pharmacists Association to receive the special rate. The deadline is Monday, May 20, 2019.

CE Topics

- MD Board of Pharmacy-approved Contraceptive Training
- Preview of 2019 Flu Season
- Hepatitis C
- New Drug Updates
- MPhA History
- Keynote Speaker
- Medical Spanish
- Transition of Care in the Community Setting
- Smoking Cessation
- Medication Safety
- Naloxone Project in Retail Pharmacies
- Vaccination Updates
- Substance Abuse
- Lactation
- Female Athlete Triad
- Transplant
- Pharmacogenomics! What's in Your Genes
- Psychopharma Catastrophes! Medication Misadventures in Mental Health
- Breast Cancer Treatment Innovation

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Standout Handout

Updates: CHEST Guideline 10th Edition, 2018 Antithrombotic Therapy for Atrial Fibrillation

Aylin Unal, PharmD Candidate 2019
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All authors involved with this research have read and reviewed the MPhA journal submission guidelines and have no conflicts of interest to disclose.

Stroke Risk in Atrial Fibrillation (AF)

For patients with AF, including those with paroxysmal AF, stroke risk should be assessed using the CHA2DS2-VASc score. Those who are at low risk for stroke (i.e. CHA2DS2-VASc score of 0 in males or 1 in females) should not receive antithrombotic therapy. Those with a score of > 1 in males or > 2 in females should be on an oral anticoagulant (OAC).

C	Congestive heart failure/ left ventricular dysfunction	1 point
H	Hypertension	1 point
A_2	Age > 75	2 points
D	Diabetes mellitus	1 point
S_2	Stroke/ TIA/ thromboembolism	2 points
V	Vascular disease*	1 point
A	Age 65–74	1 point
Sc	Sex category (female)	1 point

* *Myocardial infarction (MI), peripheral artery disease (PAD), and/or aortic plaque*

Bleeding Risk in AF

The HAS-BLED score is recommended as a bleeding risk assessment and should be performed in all patients with AF at every patient contact. Those with a HAS-BLED score > 3 are potentially at high risk and should be reviewed and followed-up more frequently. Modifiable risk factors should be addressed for any patient treated with antithrombotic therapy.

H	Hypertension	1 point
A	Abnormal renal/liver function	1 point each
S	Stroke	1 point
B	Bleeding tendency or predisposition	1 point
L	Labile INRs	1 point
E	Elderly (Age > 65)	1 point
D	Drugs or alcohol use	1 point each
Sc	Sex category (female)	1 point

Modifiable Bleeding Risk Factors:

- *Uncontrolled blood pressure*
- *INR control (target 2.0-3.0), time in therapeutic range (TTR) > 65%*
- *Excessive alcohol intake (> 14 Units/week)*
- *Concomitant use of NSAIDs or aspirin (in an anticoagulated patient)*

Anti-Thrombotic Therapy and Other Approaches for Stroke Prevention

1. Antiplatelet therapy alone is not recommended for stroke prevention, regardless of stroke risk (i.e. monotherapy or aspirin in combination with clopidogrel).
2. In patients with AF who are eligible for OAC, it is recommended to use a novel oral anticoagulant (NOAC) rather than a vitamin K antagonist (VKA, i.e. warfarin).

Continued on next page

a. "*Remark:* Patient and caregiver preferences, cost, formulary considerations, anticipated medication adherence or compliance with INR testing and dose adjustment should be incorporated into clinical decision-making."[1]

3. Patients on VKA therapy, it is recommended to aim for high-quality anticoagulation control. This is reflected by a TTR of > 70% and a target INR of 2.0-3.0. If the quality of VKA therapy is poor (e.g. TTR < 65%), it is recommended to consider interventions to improve TTR or switching to a NOAC.

a. *Remark:* Recommend interventions to improve control such as more regular INR tests, review medication adherence, address other factors known to influence INR control i.e. drug-drug interactions, and further education and counseling.[1]

4. "In patients with prior unprovoked bleeding, warfarin-associated bleeding, or at high risk of bleeding, [it is suggested] using apixaban, edoxaban, or dabigatran 110 mg (where available) as all demonstrate significantly less major bleeding compared with warfarin."[1]

Adjusted-Dose Oral VKA Therapy:

- For patients on VKA therapy with non-valvular AF, target INR should be 2.0-3.0 with attention to individual TTR, ideally > 70%.[1]
- *Importance of TTR INR Range:*
  - i. TTR is a validated measure of anticoagulation control and predicts adverse events in patients receiving VKA. Anticoagulation clinics are using TTR as a quality and performance measure of choice.
  - ii. TTR is calculated using the Roosendaal method of linear interpolation between 2 consecutive INR values.
  - iii. Limitation: "INRs > 42 days apart [have] not been interpolated in studies due to large uncertainties in fluctuation."[1]
  - iv. An individual TTR of at least > 65% has demonstrated a lower risk of thromboembolism, major bleeding, and death.[1]

AF and Chronic Kidney Disease (CKD):

- Suggested algorithm for the decision-making process in prescribing OAC therapy in patients with various degrees of renal function impairment.[1]

<table>
<tr><th>Drug</th><th>CrCl > 50 mL/min</th><th>CrCl 30-49 mL/min</th><th>CrCl 15-29 mL/min</th><th>CrCl < 15 mL/min or ESRD on RRT</th></tr>
<tr><td>VKA</td><td colspan="4">If TTR > 70%</td></tr>
<tr><td>Dabigatran</td><td colspan="2" rowspan="2">150 mg BID (or non-US 110 mg BID)</td><td>X (Outside US)
75 mg BID in US</td><td rowspan="2">X</td></tr>
<tr><td>Rivaroxaban</td><td>20 mg QD</td><td>15 mg QD</td><td>15 mg QD</td></tr>
<tr><td>Apixaban</td><td>5 mg BID</td><td>5 mg BID</td><td rowspan="2">2.5 mg BID</td><td>X (Outside US)
5 mg BID in US</td></tr>
<tr><td>Edoxaban</td><td>60 mg QD</td><td>30 mg QD</td><td>30 mg QD</td><td>X</td></tr>
</table>

CrCl = creatinine clearance; ESRD = end-stage renal disease; RRT = renal replacement therapy; BID = twice daily; QD = once daily; US = United States.

REFERENCES

1. Lip GY, Banerjee A, Boriani G, et al. Antithrombotic Therapy for Atrial Fibrillation. Chest. 2018; 154(5):1121-1201. doi:10.1016/j.chest.2018.07.040.

Continuing Ed

Pharmacist Prescribing of Contraception in Maryland

Erin VanMeter, PharmD, BCACP, University of Maryland School of Pharmacy

Learning Objectives

1. Identify the steps required for pharmacist prescribing of contraception in Maryland
2. Determine if a patient is eligible for pharmacist prescribed contraception
3. Recognize key differences between the contraceptive products that pharmacists are eligible to prescribe
4. Identify appropriate counseling points for the safe and effective use of pharmacist prescribed contraception

Kewords

- Pharmacist-prescribing
- Contraception
- Counseling

Please visit the MPhA webpage at www.marylandpharmacist.org for additional resources related to pharmacist prescribing of contraceptives in Maryland.

Introduction/Background

Approximately 50% of pregnancies in the United Stated are unintended and carry significant health and financial consequences.[1-2] Unintended pregnancies have been shown to increase the risk for poor maternal and infant outcomes. Over half of the $40.8 billion dollars spent for all publicly funded (e.g. Medicaid) pregnancies in 2010 were to cover medical costs associated with unplanned pregnancies.[2-4] Hormonal contraceptive methods have been shown to be effective at preventing pregnancies with a typical failure rate of 0.01 – 8% depending on the type of hormonal contraceptive. However, multiple barriers to obtaining hormonal contraception still exist for many women, including: difficulty obtaining an appointment with a healthcare provider, long wait times, high co-pays, inconvenient clinic hours, or wanting to avoid a pelvic examination.[6-8] Access and cost of hormonal contraceptives are among the most common reasons for nonuse or gaps in contraception use.[7-9] In fact, a survey of women aged 18–44 years old in the United States who are at risk for unintended pregnancy demonstrated that one out of four women experienced challenges in obtaining a new prescription or a refill for hormonal contraception.[9]

In 2012, the Contraceptive Coverage mandate under the Affordable Care Act (ACA) aided in making hormonal contraceptives more affordable for most women. In October 2017, the Departments of Health and Human Services, Treasury, and Labor issued regulations that significantly broadened exemption from providing hormonal contraceptive coverage for employers with a religious or moral exemption. These regulation were put into effect November 2018. Currently, thirty states and the District of Columbia (D.C.) require insurance plans to cover hormonal contraceptives.[10]

Considering varying coverage of hormonal contraceptives in the nation, and barriers to obtaining, community pharmacists are poised to have a significant role in women's access to hormonal contraception. Community pharmacists prescribing of hormonal contraception can increase access, as community pharmacies have longer operating hours, convenient locations, and generally no appointment is required to see the pharmacist.

Currently, six states have passed legislation that allows pharmacists to prescribe hormonal contraception, with several other states working on similar legislation. The following states have passed such legislation in the United States, California in 2013, Oregon in 2015, Colorado in 2016, and New Mexico, Maryland and Hawaii all in 2017.[11] In Maryland, as of January 1, 2019 pharmacists who meet the requirements of the Maryland State Board of Pharmacy regulation can prescribe and dispense Board specified hormonal contraceptives. This article will review the regulation set forth by the Maryland State Board of Pharmacy surrounding pharmacist prescribing of contraception, the necessary

requirements for pharmacist prescribing, a brief overview of contraceptive medications, and important patient counseling information. For the purpose of this publication any mention of contraception from this point forward will be referring to hormonal contraception unless otherwise stated, and pharmacists will be referring to pharmacists who are licensed to practice pharmacy in the state of Maryland.

Maryland Regulations

Following the passing of Maryland Senate Bill 363 (2017), the Maryland Board of Pharmacy (MBP) and other stakeholders began working on implementing this regulation. In February 2018, *COMAR 10.34.40 Pharmacists Prescribing Contraceptives* was approved and adopted into the regulations.[12,13]

The complete regulation, 10.34.40 Pharmacists Prescribing Contraceptives, is located on the Maryland Department of Health's website. This new regulation allows qualified pharmacists to prescribe contraceptive medications and self-administered contraceptive devices approved by the U.S. Food and Drug Administration (FDA). In order to be qualified, a pharmacist must satisfy the following requirements:

I. Complete a MBP approved training program for prescribing contraceptives
   a. Submit a notification form, which includes an attestation of completion of said program at least 15 days prior to prescribing contraceptives to the MBP;

II. Receive a written confirmation from the MBP accepting the notification prior to prescribing contraceptives;

III. Obtain the completed MBP approved self-screening risk assessment questionnaire (SSRAQ) from the patient prior to prescribing contraception for the first time and annually;

IV. Perform a blood pressure screening on the patient prior to prescribing contraception for the first time and annually;

V. Utilize and follow the MBP approved standard procedure contraceptive algorithm;

VI. Upon completion of all requirements established by the MBP and after review of all relevant information, a

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pharmacist must provide the patient with a visit summary and copy of their completed SSRAQ; and,

VII. Earn 1 hour of MBP-approved continuing pharmaceutical education related to contraception prior to their pharmacist renewal date.

The only exception to the requirements above is that completion of a training program may be waived for pharmacists who have completed such training as a part of their doctoral education program.[13] However, the same notification form, which includes an attestation of receiving this training during their formal education program is still required at least 15 days prior to prescribing contraceptives.

At minimum, a MBP-approved training program is required to contain an overview of (1) contraceptive medications and self-administered contraceptives; (2) the SSRAQ; (3) the standard procedure contraceptive algorithm; and (4) the U.S. Medical Eligibility Criteria for Contraceptive Use (US MEC) and other Center for Disease guidance on contraception.[13]

A MBP approved SSRAQ and an algorithm for Maryland pharmacist prescribing of contraceptives is available on the Board of Pharmacy website.[13,14] These documents were designed to aid pharmacists in quickly and accurately determining which patients are candidates for contraception and which are at an increased risk of experiencing adverse effects and should be referred to a primary care or reproductive healthcare provider prior to initiation of contraception. The SSRAQ includes questions that inquire about the patient's chance of current pregnancy past medical and medication history, contraceptive history, and preferred method of contraception. Questions focus on medical conditions that would disqualify women from safely using contraceptives such as venous thromboembolism (VTE), tobacco use, migraines with aura, and those at high risk for atherosclerotic cardiovascular disease (e.g. hypertension, diabetes, high cholesterol). As part of the overall patient assessment, the pharmacist must record the patient's blood pressure and weight on the SSRAQ form. As the pharmacist reviews the patient's self-assessment s/he would use the prescribing algorithm to determine if the patient is a candidate for contraception. If the patient is not an appropriate candidate for pharmacist prescribed contraception, the pharmacist should make a referral for a primary care or reproductive healthcare provider for further evaluation prior to initiation of contraception. If the patient does not have a healthcare provider, the pharmacist should provide the patient with information regarding local primary care, family planning, or reproductive healthcare providers.

As set forth by the MBP, the standard operating procedures requires the pharmacist prescribing contraceptive to (1) obtain a completed MBP approved SSRAQ from all new patients and established patients at least annually; and (2) utilize and follow the MBP approved algorithm for prescribing contraceptives to determine if it is clinically appropriate to prescribe contraception.[13] If contraception is prescribed, the pharmacist must (1) refer the patient to their primary care or reproductive healthcare provider for on-going care and to receive recommended preventative health screenings (e.g. pap smear) or provide information to family planning or reproductive healthcare provider for patients who are not currently established with one of these healthcare providers; (2) provide a visit summary and encounter documents included the SSRAQ to the patient (full requirements provided in Table 1); and (3) document the encounter and maintain the required documentation for a minimum of 5 years at the pharmacy.[13] A summary of the required documentation that is to be kept is provided in Table 1. If after review of the SSRAQ and completion of the patient assessment the pharmacist deems it clinically inappropriate to prescribe contraception s/he must provide the patient with a visit summary that includes the clinical reason why contraception will not be prescribed. Board approved visit summary sheets for patient who are and are not candidates for contraception are available on the Boards website.[14]

Once the pharmacist deems a patient an appropriate candidate for contraception s/he must then use their clinical judgement to select the best contraceptive product for the patient. Pharmacists should consider the patient's medical history, potential drug interactions, patient's preference, prior use of contraception, previously experienced adverse drug effects, likelihood of adherence, and cost when determining which contraceptive product to initiate or continue. Per the MBP regulation, pharmacists can prescribe up to 12 months of the contraception; however, the quantity should be based on professional judgment.[13,14] Resources are available to aid pharmacists with their selection of contraception. The US MEC and Selected Practice Recommendations (US SPR) for Contraceptive Use, 2016 are two notable resources that pharmacists should be familiar with to ensure safe and effective prescribing.[15,16] These references and several others are outlined in Table 2.[15-20]

Pharmacists prescribing contraception should be familiar with circumstances and conditions in which a patient would not be a candidate for pharmacist prescribed contraception and should be referred to a primary care or reproductive healthcare provider. The prescribing pharmacist should refer patients if (1) pregnancy cannot be reasonably ruled out; (2) the patient has a high risk for, past history of, or current VTE; (3) has a contraindicated medical condition or medication; (4) has an allergy to contraceptive medications; or (5) has previously been told to avoid using contraceptive pills, patches, or vaginal ring by a healthcare provider.

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Table 1: Regulations set forth by the 2018 COMAR 10.34.40 Pharmacists Prescribing Contraceptives

Information that must be included in the visit summary
• Information on the importance of seeing a primary care or reproductive healthcare provider for the recommended tests and preventative screenings • A copy of the record of the encounter that includes the patient's completed self-screening risk assessment questionnaire (SSRAQ) • A record of the contraceptive dispensed or clinical reasoning why contraception was not dispensed
Record keeping
• The pharmacy whose pharmacists prescribe contraceptive must maintain in electronic or other form documentation for a minimum of five years • Documentation must include the following: a) The type of contraceptive prescribed and dosage, or if applicable, the basis for not prescribing contraception; b) The name, address, and date of birth of the patient; c) The name of the pharmacist who prescribed the contraceptive or deemed the patient ineligible for contraception; d) The date the contraceptive was prescribed or not prescribed; e) A copy of the patient's visit summary; f) A copy of the patient's self-screening risk assessment questionnaire (SSRAQ); and g) The name and address of the: • Patient's primary care practitioner or reproductive healthcare practitioner, if provided by the patient; or • Family planning provider or licensed clinician who provides reproductive healthcare services referred by the pharmacist, if the patient does not have a primary care practitioner or reproductive healthcare practitioner.

Source: Reference 13

The algorithm for Maryland pharmacist prescribing of contraceptives outlines several contraindicated medical conditions and medications for prescribing pharmacist (Table 3).[13] The U.S. MEC, 2016 provides more detailed information on which medical conditions and medications would exclude patients from receiving contraception. Pharmacists should review and become familiar with this information prior to prescribing contraception. Additionally, the pharmacist should use their professional judgment and consider referring a patient if (1) the patient has not been seen by a physician or other reproductive healthcare provider in the past year (2) the blood pressure is > 140/90 mmHg; (3) there are multiple risk factors for atherosclerotic cardiovascular disease (ASCVD) present; or (4) the patient is over the age of 35 and uses tobacco products.[13]

In addition to this new regulation, also effective January 1, 2019, qualified pharmacists and pharmacies may enroll with Maryland Medicaid as a Pharmacist prescriber in order to receive reimbursement for the patient assessment rendered in order to determine whether to prescribe contraceptives and which contraceptive to prescribe. At the time of this writing it appears that no other insurance companies are providing reimbursement for these services. For more information on how to register with Maryland Medicaid for reimbursement of services please refer to the Board's website at: https://health.maryland.gov/pharmacy/Pages/Contraception-Prescribing.aspx. It should be noted that pharmacist prescribing of the contraception will not change the patient's insurance coverage, meaning the same coverage applies as if the prescription were written by a physician or other authorized healthcare provider.

Contraceptive Overview:

While contraceptive use is generally safe and effective, the risk associated with this class of medications should not be taken lightly.[21] The prescribing pharmacist should always assess the following before prescribing contraception (1) pregnancy status; (2) blood pressure; and (3) past medical and medication history, in addition to the information required by their State Board of Pharmacy.[14,15,22,23]

Patients are considered "reasonably not pregnant" if they lack any sign or symptoms of pregnancy and meet at least one of the criteria listed in Table 4.[14,17] As there are some cardiovascular risks associated with contraception use, the patient's blood pressure should be assessed before contraception is prescribed. Patients with elevated blood pressures (>140/90 mmHg) or multiple risk factors for ASCVD should be referred to their primary care provider for further evaluation prior to initia-

tion of contraception.[15,16] According the MBP's regulation a pharmacist may choose to take a second blood pressure reading if the initial reading is elevated.[13] The pharmacist should review the patient's past and current medical conditions, as well as current medications with care to ensure that the benefits of contraception use outweigh the associated risks.

There are numerous oral contraceptive products available and pharmacists should be aware of the differences among these products to aid in their recommendations when prescribing contraception. The primary mechanisms of action are to inhibit ovulation, produce an endometrium that is not receptive to ovum implantation, and thicken cervical mucus to inhibit sperm transport.[23] There are currently two main types of oral contraception (1) combined oral contraception (COCs), which contains estrogen and progesterone; and (2) progestin-only contraception (POPs), which only contains progesterone. Combined oral contraception is available in monophasic or multiphasic formulations. Monophasic formulations have the same amounts of estrogen and progesterone in the 21 days of active tablets followed by seven days of non-hormonal tablets, during which menses begins.[23] Multiphasic includes biphasic, triphasic, and quadriphasic formulations and can have varying amounts of estrogen and progesterone in the active tablets.[23] The multiphasic formulations were developed to try and mimic the natural fluctuations in hormones during the menstrual cycle and minimize adverse effects.[23] There are a few formulations that allow for extended-cycle or continued-cycle dosing. Extended-cycle contraception provides 24 days of active tablets followed by only four days of non-hormonal tablets, while continued-cycling provides 84 days of active pills followed by seven days of non-hormonal tablets. These products were designed to shorten duration and reduce frequency and severity of menses.[23] There is no data that demonstrates superiority of one COC in terms of efficacy or safety compared to the others.[15,16,23] As COCs have similar efficacy and safety profiles, product selection should be based on the patient's medical history and preference, previous experience, cost, and product-related factors to minimize risk of adverse effects. In general, COC products containing less than 35 mcg of ethinyl estradiol (EE) with either levonorgestrel or norethindrone should be considered first.[15,23] Progestin-only contraception should be administered daily without interruption. In fact, even small changes in administration timing can reduce efficacy.[15,23,24] Therefore, it is essential to educate patients on the importance of taking the POPs at the same time each day and when back-up

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Table 2: Resources for prescribing contraceptives

Resource	Summary	Reference Link
US MEC for Contraceptive Use, 2016[15]	• Recommendations on specific contraceptive methods for women and men who have certain characteristics or medical conditions • Examinations and test suggested prior to initiation • Available forms of contraception • Initiation methods • Management of adverse effects • Summary of available evidence	• US MEC for Contraceptive Use (2016) Online Resource
US SPR for Contraceptive Use, 2016[16]	• Safe and effective use of contraceptive methods • Available forms of contraception • Initiation methods • Management of adverse effects • Emergency contraception	• US SPR for Contraceptive Use (2016) Online Resource
CDC quick reference guides[17-19]	• How to reasonably ensure a woman is not pregnant[17] • Initiation methods and recommended follow-up[17] • How to address missed for late administration, application, or vaginal insertion[18] • Management of adverse effects[19]	• When and How to Start Quick Reference Guide • Addressing Late or Missed Dose(s) Quick Reference Guide • Management of Women with Bleeding Irregularities Quick Reference Guide
CDC Contraceptive Guidance for Healthcare-Providers[20]	• CDC summary page of available resources • CDC developed Contraception app – Integrates US MEC and US SPR recommendations – Provider-tools to assist with assessment, follow-up missed doses, adverse effects, and family planning	• CDC Contraceptive Guidance for Health Care Providers

contraception should be used in the event of a late or missed dose.[18,23] For women who breastfeeding POPs are the preferred form of oral contraception.[15,23] Although pharmacists do not have the authority to prescribe long-acting reversible contraceptives (LARCs), they should have an understanding of this form of contraception, be able to counsel patients on these agents, and refer interested patients to a clinician who could provide this form of contraception. LARCs have the lowest failure rate (0.05–0.8%) among hormonal contraceptives, as they provide prolonged contraception for 3–10 years.[16,23,24] Additionally, LARCs are strongly recommended by The American College of Obstetricians and Gynecologist (ACOG), as they are considered the most effective reversible contraceptive option for most women.[24]

Pharmacists will also have the authority to prescribe self-administered contraception including intravaginal contraception and the transdermal patch. Both the intravaginal contraception and transdermal patch release estrogen and progesterone into the body.[15,25] Until last year there was only one FDA approved intravaginal contraceptive ring, NuvaRing®, available in the United States. In August of 2018, the FDA approved Annovera®, the first intravaginal contraceptive ring that can be used for 12 consecutive months and is expected to be available later this year.[26] Currently, there is only one FDA approved transdermal contraceptive patch, Xulane® formerly known as Ortho Evra®, available in the United States. Women using the patch may be exposed to greater plasma concentrations of estrogen — up to 60% more — compared to oral formulations containing 35mcg of EE due to the transdermal system eliminating first-pass metabolism.[23] Although it has not been confirmed that increased exposure to estrogen increases risk of adverse drug effects (ADEs) such as VTE, this form of contraception may not be the best choice for patients who are at a higher risk for experiencing ADEs.[15,23] Additionally, use of the patch should be avoided

Table 3: Contraindicated medical conditions and medications as indicated by the algorithm for Maryland pharmacist prescribing of contraceptives

Medical Conditions	Medications
• Breast or other estrogen/progesterone dependent cancers • Venous thromboembolism • Atherosclerotic cardiovascular disease • Migraines with aura • Gastric bypass or other weight loss surgery • New or change in vaginal bleeding • History of organ transplant • Lupus • Hepatitis/liver disease/cancer • Gall bladder disease	• Phenytoin • Primidone • Phenobarbital • Barbituates • Carbamazepine • Oxcarbazepine • Topiramate • Lamotrigine • Rifampin/rifabutin • Felbamate • Griseofulvin • Lumacaftor/ivacaftor • Fosamprenavir • SSRIsA • Antiretrovirals • Antiparasitics • Antifungals • Antimicrobials • St John's Wort
• A detailed overview of these conditions and medications is provided in the US MECB	

Source: Reference 13 & 14 | [A]SSRI: Selective serotonin reuptake inhibitor | [B]USMEC: U.S. Medical Eligibility Criteria for Contraceptive Use, 2016

Table 4: Criteria to determine if a woman is reasonably not pregnant

The women must lack any signs or symptoms of pregnancy and meet at least one of the criteria listed in below:
• Is 4 weeks postpartum • Is <6 months postpartum, is breastfeeding >85% of feeds, and has not had a menstrual period since delivery • Seven days or less has passed since spontaneous or induced abortion • Has taken emergency contraceptive in the last 5 days (efficacy may be reduced in women >73 kg) • Last menses started within past 7 days • Has not had sexual intercourse since last menses • Has been using a reliable form of contraception correctly and consistently

Source: Reference 14, 15, & 17

in patients over 198 pounds (90 kilograms) as there is evidence of reduced efficacy in this patient population.[15,23,25]

Common adverse effects of COCs include nausea, vomiting, breast tenderness, weight gain, acne/oily skin, and breakthrough bleeding/spotting.[23] Although serious adverse events are rare, the patient's risk of VTE, myocardial infarction, and stroke increase with use. On the other hand, to put these risks into perspective a woman's risk of VTE is greater during pregnancy or in the postpartum period than that associated with contraception.[15,27] Doses of EE over 35 mcg have also been associated with an increase in adverse effects.[15,23] Adolescents, women weighing less than 110 pounds (50 kilograms), women over the age of 35, or perimenopausal women are more like to experience adverse effects; therefore, lower doses of EE should be used initial-

lyinitiallyinitially.[23] Progestin-only contraception's (POPs) have been associated with irregular bleeding which tends to resolve after the first year of therapy.[23,25] Table 5 provides additional information on adverse effects related to contraception and tips for managing adverse effects, respectively. Pharmacists should always review the current medications, over-the-counter products, herbals, vitamins, and supplements that a woman is taking to evaluate for potential drug interactions as both estrogen and progesterone undergo metabolism by the cytochrome P450 3A4 isoenzyme.[23] Contraindications to contraception have previously been reviewed and area summarized in Table 3.[14,15]

Patient Counseling

To maximize efficacy and minimize risks associated with contraceptive use, it is imperative for the prescribing pharmacist to provide patient counseling to all patients who receive contraception. Keep in mind that patients who are prescribed contraception by a pharmacist may not receive education in a timely manner from another healthcare provider. A summary of key counseling points is provided in Table 6. Four main topics that should be covered during each patient counseling session include: (1) importance of adherence and risks associated with non-adherence; (2) contraception initiation; (3) appropriate action to take in case of a missed dose; and (4) how to monitor for adverse drug effects and when to seek medical attention.

As there can be serious health and mental health consequences associated with unplanned pregnancy, it is essential for pharmacists to explain the risk for pregnancy if the

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contraception is not taken/used as prescribed. The pharmacist could assist the patient in brainstorming strategies to aid with adherence. Some strategies to maintain consistent adherence with contraception include (1) setting a daily or weekly reminder; (2) associate taking/insertion/application of the medication with a daily or weekly activity (e.g. dinner or a routine Sunday activity); or (3) dispensing at least a three-month supply.[28]

Initiation of oral contraception should be based on patient's preference, as there a several different ways in which oral contraception can be initiated. The CDC recommends using the "Quick Start" method, in which patients begin the contraception immediately.[16,17] There is some evidence to suggest that this method increases success of initiation and continuation of the contraception for at least three months.[23] Another method is "Sunday Start" in which the patient starts contraception the Sunday after their menstrual cycle begins.[23] The other potential method for initiation is the "First-day Start" in which patients start contraception on the first day of their next menstrual cycle.[23] Patients should also be educated that if the contraception is started greater than five days after menses starts, they should use back-up contraception or abstain from sexual intercourse for seven days if using a COC or two days if using a POP.[16,17,23]

The intravaginal contraception, NuvaRing®, should be inserted on or before the fifth day of the menstrual cycle, remain in place for three weeks, then removed and discarded. A new intravaginal ring should be

Table 5: Adverse Effects of Estrogen and Progesterone and Consideration for Management

Adverse Effects	Management
Estrogen Excess: • Nausea • Breast tenderness • Headaches	• Decrease estrogen content in COCs • Consider POPs or intrauterine device (IUD)
• Dysmenorrhea • Menorrhagia • Uterine fibroid growth • Cyclic weight gain due to fluid retention	• Decrease estrogen content in COCs • Consider extended- or continuous-cycle COCs • Consider POPs or intrauterine device (IUD) • NSAIDs for dysmenorrhea
Estrogen Deficiency: • Vasomotor symptoms • Nervousness • Reduced libido • Early-cycle (days 1–9) breakthrough bleeding or spotting	• Increase estrogen content in COCs
• Absence of withdrawal bleeding (amenorrhea) while taking the non-hormonal tablets	• Exclude pregnancy • Increase estrogen content in COCs if menses is desired • No adjustment if amenorrhea is acceptable to patient
Progestin Excess: • Increased appetite • Weight gain • Bloating • Constipation • Depression • Fatigue • Irritability	• Decrease progestin content
• Acne • Oily skin • Hirsutism	• Decrease progestin content • Choose a less androgenic progestin
Progestin Deficiency: • Dysmenorrhea • Menorrhagia	• Increase progestin content • Consider extended- or continuous-cycle COCs • Consider POPs or IUD • NSAIDs for dysmenorrhea
• Late-cycle (days 10–21) breakthrough bleeding or spotting	• Increase progestin content

Adapted from Pharmacotherapy: A Pathophysiological Approach (p.1317), by Shrader SP, Ragucci KR, 2009, New York, NY: McGraw-Hill, Copyright © 2009 by The McGraw-Hill Companies, Inc.

Table 6: Information that should be reviewed with patients who are receiving contraception

Patient Counseling Points:
• When to start contraception • Review proper administration and storage for the prescribed contraception • Importance of adherence and risks associated with nonadherence • Appropriate actions to take in case of a missed or delayed dose/insertion/application • When back-up contraception is required • Educate on common and serious adverse side effects • Appropriate actions to take when experiencing adverse drug effects • Educate on warning signs of serious adverse drug effects (e.g. VTE, MI, stroke) – shortness of breath, chest pain, or signs of a deep venous thromboembolism • When to call their healthcare provider, go to the emergency room, or call 911 • Educate on safe sex practices and protection against sexually transmitted diseases • Educate on benefits of health screenings and what screening would be recommended

inserted seven days later. Withdrawal bleeding is anticipated while the contraceptive ring is not inserted.[23] The intravaginal contraceptive ring Annovera® should be inserted between days two and five of the patient's menstrual cycle if starting contraception for the first time, remain in place for three weeks, then removed for seven days before re-inserting.[29] Withdrawal bleeding is anticipated during the week in which the contraceptive ring is not inserted. After Annovera® is removed from the vagina, it should be cleaned with mild soap and warm water, patted dry with a clean towel, and stored in the provided case at room temperature away from direct sunlight.[29] There are specific instructions regarding initiation of Annovera® in the manufacturer's package insert for patients who are switching from COCs or POPs.[29] The transdermal contraceptive patch, Xulane®, should be applied using the "Sunday Start" or "First Day Start" method as described above.[30] A new patch should be applied to the buttocks, chest (except the breasts), upper arm, or abdomen on the same day each week, rotating application site, for three weeks followed by a seven day patch-free period. Withdrawal bleeding is anticipated during the seven-day patch-free period.[30] Patients should be educated that if the contraception is started greater than five days after menses starts, they should use back-up contraception or abstain from sexual intercourse for seven days.[17,29,30] Please refer to the resources in Table 2 or manufacturer package insert for additional information.

Providing education to patients on how to handle missed doses, delayed insertion, or delayed application is crucial to minimizing risk of unplanned pregnancies. The CDC has two quick reference guides available for providers that outline how to handle missed doses for COCs and delayed insertion or re-insertion of intravaginal contraception and delayed application or detachment of the transdermal patch.[18] Pharmacists can also refer to the manufacturer package insert for instructions on how to handle missed doses, delayed insertion, or delayed application.

As ADEs can have a significant impact on adherence, the pharmacist should review potential ADEs that the patient may experience, as well as what steps should be taken if the patient experiences these ADEs. A list of common ADEs and recommendations for managing symptoms can be found in Table 5.[23] Patients should also receive education on signs and symptoms of serious ADEs related to combination hormonal contraception such as VTE, MI, and stroke and when to seek medical attention.

Conclusion

Between 2013 and 2017 six states have passed legislation that allow pharmacists to prescribe contraception. As of January 1st, 2019, pharmacists licensed in Maryland are eligible to prescribe contraception if they follow the regulations set forth in COMAR 10.34.40 Pharmacists Prescribing Contraceptives.

Pharmacists should be prepared to properly assess and screen patients for appropriateness of contraception, select the best product for the patient, and provide effective counseling to increase safety and efficacy of contraceptive use.

REFERENCES

1. Finer LB, Zolna MR. Shifts in intended and unintended pregnancies in the United States, 2001–2008. *Am J Public Health*. 2014;104(S1): S43-S48.
2. Gipson JD, Koenig MA, Hindin MJ. The effects of unintended pregnancy on infant, child, and parental health: a review of the literature. *Stud Fam Plann*. 2008;39:18–38.
3. IOM (Institute of Medicine), ed. *Clinical Preventive Services for Women: Closing the Gaps*. Washington, DC: The National Academies Press; 2011.
4. Guttmacher Institute. Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care. Website. https://www.guttmacher.org. Updated February 2015. Accessed January 19, 2019.
5. Centers for Disease Control and Prevention. CDC's 6/18 initiative: accelerating evidence into action. Web site. https://www.cdc.gov/sixeighteen/pregnancy/index.htm. Updated October 4, 2018. Accessed January 19, 2019.
6. Grossman D, Fuentes L. Over-the-counter access to oral contraceptives as a reproductive healthcare strategy. *Obstet Gynecol*. 2013;25(6):500–505.
7. Frost JJ, Singh S, Finer LB. Factors associated with contraceptive use and nonuse, United States, 2004. *Perspect Sex Reprod Health*. 2007;39(2):90-9.
8. Frost JJ, Singh S, Finer LB. U.S. women's one-year contraceptive use patterns, 2004. *Perspect Sex Reprod Health*. 2007;39(1): 48–55.
9. Landau SC, Tapias MP, McGhee BT. Birth control within reach: a national survey on women's attitudes toward and interest in pharmacy access to hormonal contraception. Contraception. 2006; 74(6):463–70.
10. Henry J Kaiser Family Foundation KFF. State and Federal Contraceptive Coverage Requirements: Implications for Women and

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Employers. Web site. https://www.kff.org/womens-health-policy.htm. Updated March 29, 2018. Accessed January 19, 2019.

11. National Alliance of State Pharmacy Associations. Pharmacist authorized to prescribe birth control in more states. Web site. https://naspa.us/2017/05/pharmacists-authorized-prescribe-birth-control-states/. Updated May 4, 2017. Accessed January 19, 2019.
12. Chasse J. Fiscal and policy notes: Senate Bill 363. General Assembly of Maryland Web site: http://mgaleg.maryland.gov/2017RS/fnotes/bil_0003/sb0363.pdf. Updated November 28, 2017. Accessed January 19, 2019.
13. Maryland Board of Pharmacy. 10.34.40 Pharmacist prescribing contraceptives. Maryland Board of Pharmacy Web site: http://health.maryland.gov/regs/Pages/10-34-40-.aspx. Updated February 16, 2018. Accessed January 19, 2019.
14. Maryland Board of Pharmacy. Contraception prescribing. Maryland Board of Pharmacy Web site: http://health.maryland.gov/pharmacy/Pages/Contraception-Prescribing. aspx. Accessed February 19, 2008.
15. Curtis KM, Tepper NK, Jatiaoui TC, et al. U.S. medical eligibility criteria for contraceptive use, 2016. *MMWR Recomm Rep.*2016;65(3):1-103.
16. Curtis KM, Jatiaoui TC, Tepper NK, et al. U.S. selected practice recommendation for contraception use, 2016. *MMWR Recomm Rep.*2016;65(4):1-66.
17. Centers for Disease Control and Prevention. When to start using specific contraceptive methods and routine follow-up after contraceptive initiation. CDC Website: https://www.cdc.gov/reproductivehealth/contraception/pdf/when-to-start_508 tagged.pdf. Accessed January 19, 2019.
18. Centers for Disease Control and Prevention. Recommended action after late or missed combined oral contraceptives, delayed application or detachment with combined transdermal patch, and delayed insertion or reinsertion with combined vaginal ring. CDC Website: https://www.cdc.gov/reproductivehealth/unintendedpregnancy/pdf/248124_fig_2_3_4_final_tag508.pdf. Accessed January 19, 2019.
19. Centers for Disease Control and Prevention. Management of women with bleeding irregularities while using contraception. CDC Website: https://www.cdc.gov/reproductivehealth/contraception/pdf/Management-During-Contraception_508Tagged.pdf. Accessed January 19, 2019.
20. Centers for Disease Control and Prevention. CDC contraceptive guidance for healthcare providers. CDC Website: https://www.cdc.gov/reproductivehealth/contraception/contraception_guidance.htm Updated September 18, 2017. Accessed January 19, 2019.
21. American College of Obstetricians and Gynecologists. Committee on Gynecologic Practice, Committee Opinion No. 544: Over-the-counter access to oral contraceptives. *Obstet Gynecol.*2012;120:1527-1531.
22. Anderson L, Borgelt LM, Clark P, Moore G. Encouraging comprehensive and consistent pharmacist education for provision of contraception. *J Am Pharm Assoc.*2018;58:113-116.
23. Shrader SP, Ragucci KR. Contraception. In: Dipiro JT, Talbert RL, Yee GC, et al., eds, *Pharmacotherapy: A Pathophysiological Approach.*7th ed. New York, NY: McGraw-Hill; 2009.
24. American College of Obstetricians and Gynecologists. Increasing Access to Contraceptive Implants and Intrauterine Devices to Reduce Unintended Pregnancy. ACOG Web site. https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Increasing-Access-to-Contraceptive-Implants-and-Intrauterine-Devices-to-Reduce-Unintended-Pregnancy. Updated October 2015. Accessed January 19, 2019.

Active Learning — Patient Case

Mrs. CM is a 33-year-old Hispanic female who presents to your pharmacy and she is interested in receiving a prescription for contraception. Mrs. CM states she was on birth control about six years ago and self-discontinued to have children. She gave birth to her second child 12 months ago and recently began having regular menses. She and her husband are not planning to have any more children and she would like to re-start contraception. Mrs. CM is not currently using any forms of contraception.

1. If Mrs. CM denies any signs of pregnancy which of the criteria below would also need to be present to ensure that Mrs. CM is reasonably not pregnant?

a. Mrs. CM's husband occasionally uses a condom during sexual intercourse

b. Mrs. CM has not had sexual intercourse in the past seven days

c. Mrs. CM started her menstrual cycle five days ago

d. Mrs. CM has taken emergency contraception in the past

2. You take Mrs. CM's blood pressure and obtain a reading of 142/80 mmHg. Mrs. CM seems surprised by this reading and states her blood pressure is usually 120/80 mmHg. You inquire about recent activities, she reports exercising about 20 minutes prior to coming to the pharmacy. What be the best next step to ensure Mrs. CM can safely receive pharmacist prescribed contraception?

a. Mrs. CM's husband occasionally uses a condom during sexual intercourse

b. Mrs. CM has not had sexual intercourse in the past seven days

c. Mrs. CM started her menstrual cycle five days ago

d. Mrs. CM has taken emergency contraception in the past

3. While Mrs. CM is filling out the SSRAQ you review her medication profile and notice that she routinely fills tacrolimus (Prograf®) and mycophenolate (CellCept®). According to the MBP's algorithm for Maryland Pharmacist Prescribing of Contraceptives would Mrs. CM be a candidate for pharmacist prescribed contraction?

a. No, as she would only be able to prescribed a three month supply instead of the full 12 months

b. Yes, as Mrs. CM has previously been on birth
control

c. No, as these medications are commonly prescribed after a transplant

d. Yes, as long as Mrs. CM is educated on the associated risks

4. Mr. Smith agrees to receive a dose of the Shingrix vaccine today. Which of the follow statements is true?

a. Yes, Mrs. CM is eligible for pharmacist prescribed contraception as her DVT was considered provoked

b. No, patients with history of DVT are not eligible for pharmacist prescribed contraception

c. Yes, patients who are no longer on anticoagulation are eligible for pharmacist prescribed contraception

d. No, Mrs. CM must first have a venous duplex scan to rule out recurrent DVT

5. You determine that Mrs. CM is not a candidate for pharmacist prescribed contraception. What information should be included in Mrs. CM's visit summary?

a. Names of other local pharmacies that can dispense contraception

b. Clinical reason as to why contraception is not being dispensed

c. Address and telephone number of the pharmacy

d. Non-hormonal options for contraception

Answers on page 24

25. American College of Obstetricians and Gynecologists. Combined Hormonal Birth Control: Pill, Patch, and Ring. ACOG Web site. https://www.acog.org/Patients/FAQs/Combined-Hormonal-Birth-Control-Pill-Patch-and-Ring. Updated March 2018. Accessed January 19, 2019.

26. U.S. Food & Drug Administration. FDA approves new vaginal ring for one year of birth control. FDA Web site. https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm616541.htm. Updated August 10 2018. Accessed January 19, 2019.

27. Lam Y, Coe C, Mounsey A. Which combined oral contraceptive to prescribe with CV safety in mind. *J Fam Pract*.2017;66(7):454-456.

28. Choi A, Dempsey A. Strategies to improve compliance among oral contraceptive pill users: a review of the literature. Open Access J Contracept.2014;5:17-22.

29. U.S. Food & Drug Administration. Highlights of prescribing information for Annovera. FDA Web site. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/209627s000lbl.pdf. Updated August 2018. Accessed January 19, 2019.

30. Mylan Pharmaceuticals Inc. Highlights of prescribing information for Xulane. Xulane Web site. https://www.xulane.com/-/media/xulanecom/files/neets-r14_exhibit-pdf.pdf?la=en. Updated April 2017. Accessed January 19, 2019.

ANSWERS | Active Learning — Patient Case

1 Answer: C. Before the pharmacist can prescribe contraception, it is essential to ensure that the patient is reasonably not pregnant. To be reasonably sure a patient is not pregnant she should lack any signs or symptoms of pregnancy and meet at least one of the criteria listed in Table 4. The criteria listed in Table 4 were incorporated into the SSRAQ, as well as the MBP's Algorithm for Maryland Pharmacist Prescribing of Contraceptives.

2 Answer: D. Cardiovascular risks have been associated with contraception use and the patient's blood pressure should be assessed before contraception is prescribed. According the MBP's Algorithm for Maryland Pharmacist Prescribing of Contraceptives, prescribing pharmacists may use their clinical judgement in determining if patients with elevated blood pressures (>140/90 mmHg) and/or multiple risk factors for ASCVD are eligible for pharmacist prescribed contraception. The MBP regulation also states that the prescribing pharmacist may take a second blood pressure reading if the initial reading is >140/90 mmHg. According to the American Heart Association to ensure accuracy of a blood pressure measurement it should not be taken within 30 minutes after smoking, exercise, or ingestion of caffeinated beverages. Additional, the patient should rest for at least five minutes with their arms comfortable at heart level and feet flat on the floor. As Mrs. CM reported exercising about 20 minutes early it would be reasonable to wait at least 10 minutes and obtain a repeat blood pressure measurement.

3 Answer: C. Even before the patient completes the SSRAQ, the prescribing pharmacist should review all available information to ensure safe prescribing of contraception. Tacrolimus and mycophenolate are medications commonly prescribed to patients who have undergo an organ transplant. Therefore, it would be important to clarify why the patient is taking these medications even if she does not indicate a history of transplant on her SSRAQ. According to the MBP's Algorithm for Maryland Pharmacist Prescribing of Contraceptives, patients who had an organ transplant are not eligible for pharmacist prescribed contraception and should be referred to their primary care or reproductive healthcare provider. If the patient does not have a provider, the pharmacist should provide the patient with a list of local family planning providers or licensed clinicians who provide reproductive healthcare services.

4 Answer: B. The correct answer is B. Though serious adverse events are rare, use of contraception (especially COCs) can increase a patient's risk for VTE, myocardial infarction, and stroke. Therefore, contraception use in patients with a history a VTE, even if the patient is no longer on anticoagulation, should be done with caution. Additionally, according to the MBP's Algorithm for Maryland Pharmacist Prescribing of Contraceptives, patients with a high risk for or history of VTE are not eligible for pharmacist prescribed contraception and should be referred to their primary care or reproductive healthcare provider.

5 Answer: B. According to the MBP regulation COMAR 10.34.40 Pharmacists Prescribing Contraceptives if the prescribing pharmacist determines that a patient is not eligible for pharmacist prescribed contraception, s/he must include the clinical reason as to why the patient is not eligible in the patient's visit summary. Please refer to Table 1 for a complete list of the information that is required to be included in the patient's visit summary. Additionally, the pharmacist should consider providing counseling on non-hormonal forms of contraception such as barrier methods or use of a spermicide; however, this counseling is not required under the MBP regulation.

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Directions for taking this issue's quiz:

This issue's quiz on **Pharmacist Prescribing of Contraception in Maryland** can be found online at www.PharmCon.com.

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Legislative Update — MPhA Priority Legislation

Below are status updates on MPhA's legislative and/or policy agenda. We had success in the area of increasing PBM transparency and a path forward for a Medicaid audit of pharmacy reimbursements. We have more work to do in Annapolis regarding pharmacist scope of practice. New members to the committees of jurisdiction and were hesitant to make scope changes during their first session. We will continue to education them on all the great work pharmacists do and should be doing. To view a more comprehensive status report of pharmacy-related bills visit www.marylandpharmacist.org.

Maryland Pharmacy Coalition Legislative Day on February 7, 2019

MPhA Priority — PBM Transparency and Pharmacy Reimbursements

HB 589 — Maryland Medical Assistance Program and Managed Care Organizations that Use Pharmacy Benefit Managers — PASSED

HB 754 — Health Insurance and Pharmacy Benefits Managers — Cost Pricing and Reimbursement PASSED

HB 759 — Pharmacy Benefit Managers — Pharmacy Choice PASSED

- The bills were moved through the session as a package.
- HB 589 — requires a Medicaid audit, ability for MDH to request input from CMS on alternate avenues for reimbursing pharmacies; and development of an appeals process for MCO contracts managed by PBMS.
- HB 754 —does not allow DIR or GER fees. All fees must be adjudicated at the point of sale. Standardizes the appeals process for commercial and Medicaid plans; PBMs must provide mathematical calculations in appeals denials and certain contracts and amendments are not effective unless; filed with Commissioner of the Maryland Insurance Administrator for approval or disapproval within certain time limits.
- HB 759 —PBM may not require a patient to utilize a pharmacy it has a business interest in a pharmacy or vice versa; excludes specialty drugs.

Pharmacists — Aids for the Cessation of Tobacco Product Use — Prescribing and Dispensing

HB 1217 — HELD

SB 497 — UNFAVORABLE REPORT

- The bill authorized a pharmacist to prescribe and dispense tobacco cessation aids approved by the U.S. Food and Drug Administration.
- This bill had support from the insurance community as well as the Baltimore City Health Department and the National Alliance of State Pharmacy Associations.
- Varied objections were raised from the prescriber community from concerns about side effects related to Chantix and Zyban and would only support prescriptive authority for nicotine replacement products. Others raised concerns that the practice would be done in facilities that actually sell cigarettes and felt that the legislation should not support this contradiction.
- We are working with legislators and other stakeholders with the expectation that the bill will be reintroduced in the 2020 Session. We have a commitment from the bill sponsor to continue to support the effort.

Pharmacists — Administering Injectable Medications and Biological Products

HB 419 – HELD

SB 577 – HELD

- The adds administration of injectable medications and biological products to the self-administered medications statute

- This bill had support from individual psychiatric prescribers and a broad base of national pharmacy and physician groups.
- It was amended to removed intravenous administration.
- Prescriber legislators had mixed feelings about the bill and vacillated during the session between moving forward and holding the bill.
- Prescriber stakeholders also had mixed responses, some were okay with just authorizing for psychiatric long acting injectables, while others were fine with the full scope of administration as long as it was under a collaborative practice agreement.
- We did not reach agreement on how to move forward. The bill sponsors will reintroduce the legislation next session. We will work with stakeholders over the summer to work through areas of disagreement.

Drugs and Devices — Electronic Prescriptions — Requirements

HB 409 - HELD

SB 469 - HELD

- Legislation as introduced requires e-prescribing for all prescriptions, with waivers.
- The original bill required e-prescribing for all prescriptions, but was amended to focus on controls.
- That amendment led to jurisdictional issues regarding compliance and because controlled substances are under the criminal statute as well as the term "e-prescription" is not defined in Maryland law. There was not enough time to work out the implications and have concurrence by the judiciary committee.

Pharmacy representation at the Maryland State House

Isatu Conteh, Martin Mintz, Representative Anthony Brown (MD-04), Brian Hose, and Aliyah Horton at the NCPA Fly-In in April

Changes in Maryland PDMP Dispenser Reporting Requirements

Please take note of changes impacting most pharmacies and practitioner dispensers of controlled dangerous substance (CDS) prescriptions who report data to the Maryland Prescription Drug Monitoring Program (PDMP). The PDMP is an important clinical tool for practitioners across Maryland to make informed treatment decisions; this tool is most effective when all applicable data are reported. Your timely response to these changes helps ensure that the PDMP can deliver comprehensive prescription information!

Dispensers must begin reporting data to a new data collection software product, RxGov, no later than June 1, 2019. Dispensers are required to report data every 24 hours, including zero reports, effective July 1, 2019. A summary of the changes are below, and detailed instructions for compliance are available online in the 'Dispenser Reporting' section of the Maryland PDMP website: www.MarylandPDMP.org

Data Collection Vendor Change: Maryland PDMP has contracted with a new data collection software, RxGov, which has begun accepting data submissions. Dispensers, or their authorized data submitter, must begin reporting data to RxGov by June 1, 2019. Every data submitter account currently registered with the existing RxSentry platform will be migrated to the new software, RxGov.

Daily Reporting Change: Maryland statute governing the PDMP was amended (HB437/Chapter 147, 2016) to change the dispenser reporting frequency in line with national PDMP best practices. All non-exempt dispensers of CDS medications are required to report applicable dispenses every 24 hours to the Maryland PDMP, including submission of zero reports if no dispensing occurs. 'Zero reports' will be required on any day that the dispenser does not dispense a CDS prescription, regardless of whether or not the dispensing facility is open for business that day. Monitoring for compliance with the daily reporting requirement will begin July 1, 2019.

Dispensers who submit data themselves: Dispensers who serve as a data submitter will have their accounts migrated to the new RxGov product; you will 'claim' your account by setting a new password and can begin uploading data to the new site using your existing method. A 'Data Submitter' guide will be available on the Maryland PDMP website.

Dispensers who rely on a 3rd party vendor to report data: Pharmacy and practitioner dispensers often rely on software vendors to submit dispensed CDS prescription data to the PDMP on their behalf. All data submitters currently registered with the Maryland PDMP have been notified of these two changes and provided instructions to comply. However, dispensers remain responsible for ensuring their data are submitted to the Maryland PDMP. You should contact your vendor to confirm their plans so you are not found out of compliance.

Policy questions should be directed to the Maryland PDMP at mdh.pdmp@maryland.gov or 410-402-8686, directly to PDMP Data Quality Specialist Katherine Johnson at Katherine.johnson@maryland.gov, or visit our website: www.MarylandPDMP.org. ●

Second Quarter 2019: Pharmacy Time Capsule

By: Dennis B. Worthen, PhD, Cincinnati, OH

1994

- Pharmacists Code of Ethics updated to require pharmacists to help individuals achieve optimal benefit from their medication.

1969

- APhA Code of Ethics deleted the prohibition for pharmacists to discuss therapy contents or drug actions with patients.

1944

- Hans Asperger describes Asperger syndrome.

1894

- Passage of state pharmacy act in Vermont. ●

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Executive Director's Message: Paradox of Progress

I recently heard a presentation entitled, the "paradox of progress." It talked about how your progress can sometimes be a setback, because the success may manifest itself in ways that ultimately impede additional progress — a kind of ultimate contradiction. The presentation made me think about MPhA's 136 year anniversary in May and our continued growth and successes in advocacy, outreach and education. Yet, we still remain challenged in moving a greater percentage of pharmacists, pharmacy technicians and student pharmacists in Maryland off the sidelines to being actively involved in supporting MPhA.

We had a successful run this legislative session in achieving long-needed change and exposure of how PBMs operate regarding pharmacy reimbursements within the Maryland Medicaid MCOs. We made valiant efforts to move forward on prescriptive authority and increased scope of practice for medication administration but there is more work to be done. We worked to educate newly elected members of the Maryland General Assembly and others about the role of pharmacists in their community. We have achieved gains in building MPhA's brand and recognition at the state and national level via our engagement on key issues related to opioid overdose prevention, drug safety and security, medication disposal and advancing prescriptive authority. As of this writing, I am pleased that our contraceptive training program was approved by the Maryland Board of Pharmacy. We will be moving forward with providing that training at the Annual Convention with additional resources to ensure your ability to fill this gap in women's healthcare as a reimbursable clinical service.

With that said, we often have a tendency to rest on our victories, with assuredness that others are engaged and working to advance our causes. But that makes the efforts harder and the progress slower. We cannot continue to sit back and say great job, but still wonder why more hasn't been accomplished. That is the paradox of progress. In many ways, I am preaching to the choir. As a current member of MPhA you recognize the value in your affiliation. So, I ask you to encourage your colleagues to not sit on the sidelines. We have much more work to do and it cannot be done with a few volunteers.

2019 is seeing substantial volatility in Maryland's pharmacy landscape — MPhA must change with it. We are collaborating with non-traditional organizations to open up opportunities for pharmacist employment; supporting efforts to explore alternate business models; and pushing for enhanced scope of practice to ensure that there are more options for reimbursable clinical services. At the same time, I continue to be surprised that there are practicing pharmacists who are not taking advantage of immunization certifications or pharmacies who are not providing those services. In order to move ahead, we must exhaust opportunities that are available so that we can build upon them. The effective implementation of your prescriptive authority and maximizing all the opportunities currently available demonstrate your capabilities and aid in securing other healthcare provider allies.

As we push through this "paradox," we recognize that MPhA must change and pivot to be the organization you need most. In order to do that, we must be accessible, flexible, affordable, diverse and inclusive and an entity worthy of your trust and investment. We are moving through this year reflecting on our past success and envisioning what kind of organization we will be in 2020 and for the next 100 years. Your leadership, board and staff will be conducting outreach and examining these areas to see MPhA from your viewpoint. In order to build the best value proposition, we need to understand how you want to see yourself or your business in the next few years. What do you need to achieve those goals? What barriers prevent your colleagues from being a part of MPhA? What external issues impact your ability to practice and fulfill your professional obligations?

I implore you to say what needs to be said. We are here to listen and act!

Thank you and I look forward to hearing from you and seeing you soon!

Aliyah N. Horton, CAE
Executive Director

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President's Pad

A strong logistical and event-based structure has been set up this past year. This has led to innovations in how we conduct business, share information, and represent pharmacy within the State of Maryland. We've accomplished a lot in the past year, member value offerings, and CEs being offered not just at Mid-Year and Annual Convention, but online throughout the year. We've changed membership categories to allow people to better choose what they want from MPhA. We've held 2 fantastic conventions. And we had wins in the legislature regarding Medicaid HMO reimbursement, prior authorizations, restricting fees on claims adjudication, and pharmacy choice. We also supported and won increased access to Hepatitis C medications, following one of our resolutions from last year's House of Delegates. While efforts for improving medication administration practices and smoking cessation were held over in the legislature this year, we fully intend to have some movement in this next legislative session.

One of our challenges in these efforts are other health professions associations. We need to establish better rapport with these groups.

I turn back to words from the past that still resonate in discussing this issue:

> 'Pharmacy has always been one of the subordinate departments of medicine... is an abnormal condition... The pharmacist has evolved from the pharmaceutical manipulations the physician by delegated preparing and dispensing medicines. To the busy practitioners of medicine in those days when ...preparations required much labor and mechanical skill, it was a boon to doctors, and they gladly patronized the apothecary.
>
> Presently there is much dissatisfaction between physicians and pharmacists, which is to be regretted; but this has been the case for a long time, and is likely to continue, for the reason that an partially undefined imaginary line separates the duties of the two professions with frequent temptation on the part of the members of both to invade the imaginary territory of each, and sometimes with the moral justification.
>
> The physician should regard the dispensing pharmacist as his natural ally, in so far as his professional conduct may be reliable and satisfactory ... If medical men would observe the conduct of pharmacists they would know that in every section of this State, are those who are worthy of professional recognition, and whom they can trust.'

This was from John Hancock, 13th President of MPhA in 1895. While actually making the medicinal products is not much of our work today, the premise of the division of labor and knowledge is appropriate. We are the medication experts, but we need to prove ourselves every day worthy of that title. We need to make ourselves valued members of the health care team through appropriate interactions with prescribers. We need to develop the relationships with other providers and with it, the dependency on your knowledge and skill with medications and patients. The best way for pharmacy to be involved on the progressive edge of healthcare is by repeatedly demonstrating our value – it can improve healthcare outcomes, allow us to develop and participate in new payment models, and make you feel better about your work on a regular basis.

As in 1895, we are MPhA.

Looking back again to John Hancock,

> 'Pharmacy is an occupation, requiring genius to harmonize and utilize its varied interests. Being an important branch of medicine, involving physicians and the community at large in its practice, doing good or injury, according to the methods employed, and to practice successfully more than ordinary ability is required; the successful must support the dignity of an ethical profession and **should be an active and honorable member of some Pharmaceutical Association,** and cultivate social relations with the other members of the fraternity, *and, when need be, act in unison with his brothers to defend, protect and advance the common good.*
>
> The influence of competition, the growth of knowledge, the general education of the masses, and the increase of population and poverty, with the unnecessary increase of medical mergers, together with the tendency to aggregate capital in the control of business, with the one result, to make the rich richer and the poor poorer—and has marked its imprint on pharmacy.'

Back in the 1800's just as today, it was important to be involved, to have strong ability and ethics, and to be actively involved in protecting the common good, not just of pharmacy, but of patients. And as in the 1800's just as today, we continue to struggle with challenges from consolidation of money and power in medicine. We still need to stand strong in the opposition of predatory practices driving the cost of healthcare and medicine. We will continue to work to help community pharmacies stay profitable and open for our patients and our own wellbeing and we need every pharmacist to be involved in this process. That means membership... that means outreach.

We are MPhA.

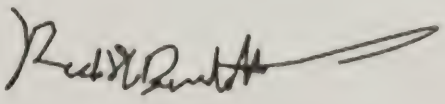
Our association has challenging decisions that we currently face to help create a fiscal fortress ensuring MPhA's existence and impact for perpetuity. Our deficit spending, while it has been decreasing, is still significant. Our endowment from the EF Kelly fund is not being used as an endowment that will last forever, but rather as a fund to balance our books. Unchecked, this will eliminate the balance in the next decade. We have a building that is mostly unused. The space is beautiful, but it is just a space. We are MPhA.

Resolving this budgetary issue is going to be a key priority of my term in office. These are not hard tasks that have been ignored over the past 5 years, in fact we've made significant strides at lowering costs over the past few years. We, as members must do some of the rest of the work, particularly in the realm of membership. We need more members and you can help by encouraging and showing the value of membership!

We are MPhA.

We work hard, we do great things, we face some challenges.

We are MPhA.



Richard DeBenedetto, PharmD, MS, AAHIVP

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Member Mentions & News You Can Use

Horton and Sample-Hughes Attend Women in Government Legislative Conference

MPhA Executive Director Aliyah Horton participated on a panel to discuss MPhA's role and the efforts of the RxALI MD to collaborate with patient advocacy, healthcare and prescriber stakeholders to reduce opioid misuse and abuse. She was also able to connect with WIG Board Member and Member of the Health and Government Operations Committee, Del. Sheree Sample-Hughes.

Yankellow, Bouyoukas, and Ashby Reappointed to Board of Pharmacy

Congratulations to Ellen Yankellow, Steve Bouyoukas, and Daniel Ashby who were recently reappointed to serve a second term on the Maryland Board of Pharmacy by Governor Larry Hogan! The three members hold at-large, chain, and hospital seats respectively. respectively. Thank you for your service!

Thank You to the MPhA Rotation Students!

Thank you to our MPhA Rotation Students for their hard work during their 2018-2019 rotations with MPhA!

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Marcus Mog
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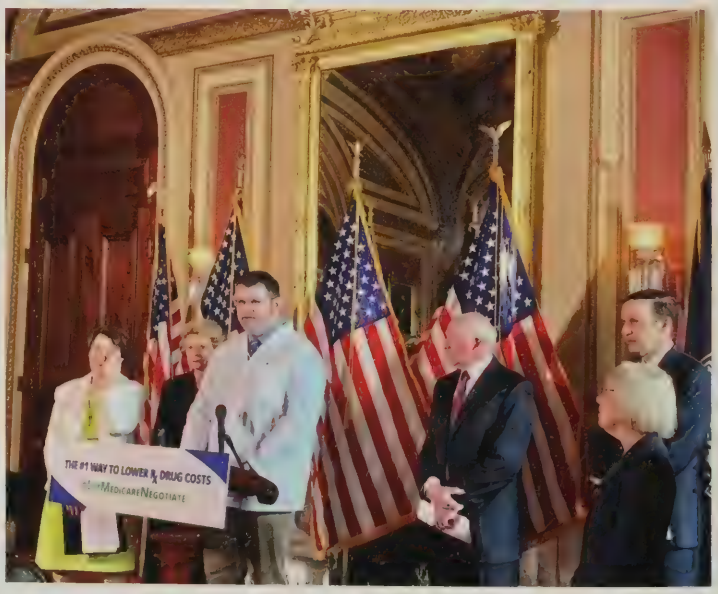
Linh Vo

Hose Speaks on Capitol Hill

MPhA Past President Brian Hose was on Capitol Hill with U.S. Senators Debbie Stabenow (D-MI), chair of the Democratic Policy and Communications Committee and Ranking Member of the Health Subcommittee of the Senate Finance Committee; Amy Klobuchar (D-MN); Patty Murray (D-WA), Ranking Member of the Senate Health, Labor, Education, and Pensions Committee; and Chris Murphy (D-CT) to discuss Medicare negotiation as a way to lower the cost of prescription drugs for millions of Americans. "Pharmacists are a vital part of any community, providing medications and patient care services that improve health," said Brian Hose, Pharm.D. and owner of Sharpsburg Pharmacy in Sharpsburg, MD. "We want solutions to lower prescription drug prices to ensure seniors get the best deal for their medications at the pharmacy counter."



MPhA and University of Maryland Awarded Two Grants

The P3 Program, a collaborative agreement between the University of Maryland School of Pharmacy and MPhA that serves as the clinical arm of the Center for Innovative Pharmacy Solutions (CIPS), recently received opportunities to provide Comprehensive Medication Management Services (CMMS) within two grant funded programs:

Totally Linked Care in Maryland (TLC-MD) – This is a collaboration of seven hospitals in southern Maryland focused on reducing 30-day hospital readmission and overutilization of acute care facilities such as the Emergency Department. Within this initiative, P3 provides CMMS during Transition of Care (TOC) when patients are discharged from the hospital to their primary residence. This program is funded by the Health Services Cost Review Commission (HSCRC).

Prevention Link of Southern Maryland – This project funded by the CDC is geared to improve health outcomes for patients at all levels of risk for chronic disease, from persons at risk for diabetes and heart disease to high-system utilizers with frequent hospitalizations. Within this program, P3 will focus on CMMS in patients with or at risk of Hypertension, Stroke, Hyperlidpidemia and overall Cardiovascular disease.

MPhA Awarded Two-Year Grant from the Cardinal Health Foundation to Help Improve Prescribing Practices for Pain Management.

MPhA received a $113,000 grant from the Cardinal Health Foundation, through its new Optimal Prescribing in Pain Management (OPPM) initiative. The funds will support an outreach, education and training initiative to raise awareness and increase collaboration between patients, prescribers and pharmacists to ultimately reduce opioid misuse and abuse. The grant program pairs schools of pharmacy with state pharmacy associations, bringing together complementary assets to address the issue. The Cardinal Health Foundation, in partnership with the National Alliance of State Pharmacy Associations (NASPA) and the American Association of Colleges of Pharmacy (AACP), is the national convener of the program.

MPhA was one of five OPPM grant recipients. The grant program is designed to prevent opioid use disorder across the state of Maryland by supporting strategies that drive optimal prescribing of pain medications and the appropriate use of opioid medications. MPhA looks forward to kicking off the program in September 2019 with all Maryland Schools of Pharmacy as partners in the initiative. If you are interested in being involved in this project, please contact aliyah.horton@mdpha.com.

MPhA *Welcomes* OUR NEWEST MEMBERS

Welcome to MPhA, we are happy to have you! If you meet these new members, please welcome them to the MPhA pharmily. Be sure to invite them to join a committee or attend a networking event!

Pharmacist

Joshua Cahill – Middle River

Leslee Donilon – Ellicott City

Megan Ehret – Monrovia

Amir Masood – Ellicott City

Krupta Patel – Sykesville

Alicia McMillan – Florida

Student

Ruth-Ann Christie – Owings Mills

Samantha Hartig – Parkville

Min Kang – Laurel

Bao-Linh Vo – Baltimore

Scott Meyers – Baltimore

Ayesha Nasir – Burke

Ogechi Obi – Salisbury

Michael Okebuguwa – District Heights

Umar Qazi – Baltimore

Heidy Rivera – Baltimore

Jennifer Sequera – Frederick

Convention Wrap Up

Thank you to all who attended MPhA's 137th Annual Convention in Ocean City, MD! And thank you to the Meeting Planning Committee, led by Yen Dang and Virginia Nguyen for putting together a great program of continuing education, networking, and fun! ●

Recognitions

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All awardees are pictured with MPhA President Chai Wang (2018–2019) unless otherwise noted.

Bowl of Hygeia winner Matthew Shimoda, PharmD

MPhA Seidman Distinguished Achievement Award winnter Stephen Wienner

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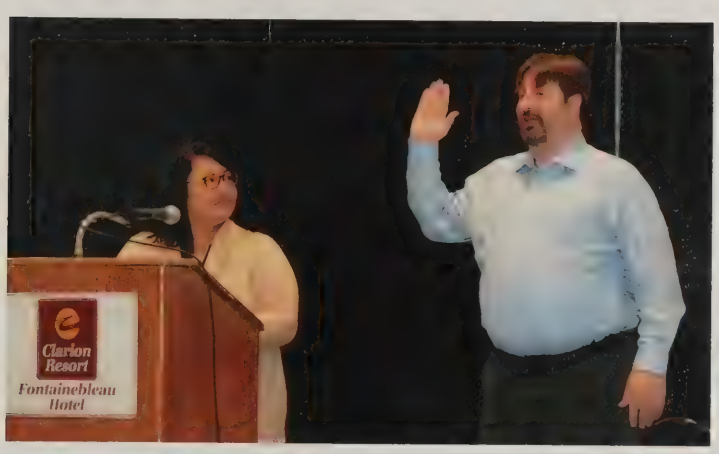
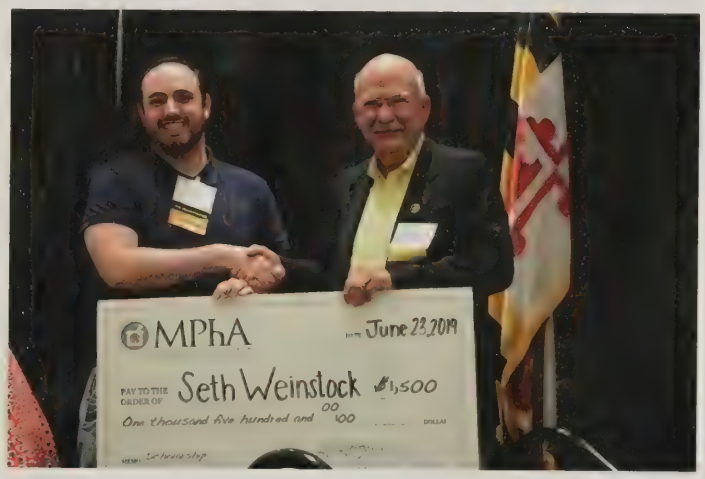


Swearing in of the new President, Richard DeBenedetto

MPhA Mentor Award winner Lynette Bradley-Baker

Excellence in Innovation Awardee, Kathleen Pincus, presented by G. Lawrence Hogue, MPhA Foundation President.

MPhA Distinguished Young Pharmacist Award winner Lauren Lakdawala presented by Pharmacists Mutual



Scholarship winner Seth Weinstock presented by G. Lawrence Hogue, MPhA Foundation President. Additional winners Ankit Shah and Elodie Tendoh (not pictured).

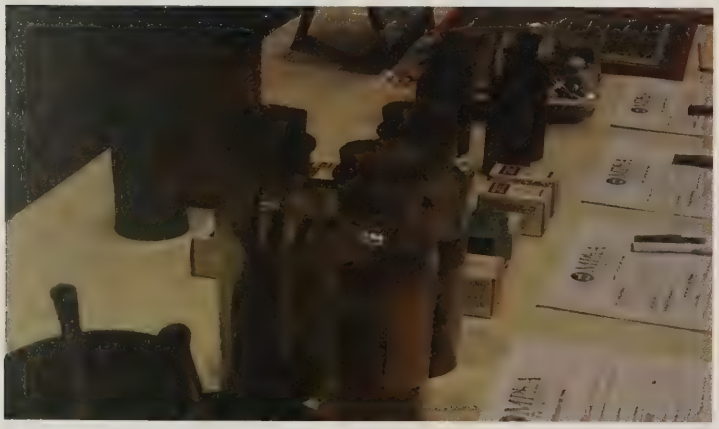
Photography Credit: Marci Strauss

Honorary President, Delegate Nicholaus Kipker

Pharmacist Advocate Award winner Brian Hose

Outgoing Chairman Cherokee Layson-Wolf and Outgoing President Chai Wang

Outgoing Speaker of the House Matthew Balish



Policy Actions | The following policies were passed in the 2019 MPhA House of Delegates

Controlled Substance Dispensing

MPhA supports pharmacists using their professional responsibility in dispensing opioids. Opioids should be dispensed in the minimum amount required to ensure appropriate pain relief through the use of the following resources and strategies:

1. Use prescription drug monitoring program (PDMP) to ensure patients are seeking care from an appropriate number of prescribers and pharmacies

2. Promote continuing education regarding pain management to assess treatment and engage in discussions with prescribers as appropriate.

3. Identify behaviors that might suggest potential opioid misuse and use motivational interviewing techniques to support patient needs

4. Collaborate with providers for referrals to pain specialists or treatment centers to support patient needs as appropriate.

5. Educate patients on availability of naloxone via the State standing order

Pharmacist care in patients using cannabidiol products

1. MPhA recognizes that the chemical compound cannabidiol is both a health supplement and prescription entity approved by the FDA. This product in its many forms can have drug-drug interactions that require pharmacist prospective drug review to mitigate adverse drug events.

2. MPhA advocates for pharmacist consultation on proper use and provision of prospective drug review to prevent medication misuse.

3. MPhA will continue to educate its members on cannabidiol changes in legal status, as well as the pharmacology and evidence regarding benefits, indications, potential for addiction and other scientific developments.

Access to medical cannabis records at pharmacies

MPhA advocates for pharmacies in Maryland having access to medicinal cannabis approval and dispensing records.

2. MPhA advocates for cooperation and transparency in Maryland law regarding the use of medical cannabis and sharing of data from dispensaries to pharmacies.

3. MPhA supports sharing of medical cannabis use information within the pharmacy record to include documentation of dispensary using and what current THC or CBD containing products are being used.

Misrepresentation of businesses supplying medical cannabis and cannabidiol products

1. MPhA opposes the use of any business entity furnishing medical cannabis or cannabidiol products that is not a licensed pharmacy with the nomenclature of "Pharmacy," or any phonetic derivative, "drug, drug store, medicine, medicine shop, apothecary, chemist, chemist shop' or other related derivatives to ensure the public can safely identify where a licensed pharmacist is available for consultation.

2. MPhA encourages the investigation of use of these terms by business entities in Maryland and referral to appropriate government agencies.

A proposed resolution on Pharmacy association membership was referred back to the Resolutions Committee.

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Editorial

Love Them, Protect Them, Always Inject Them: Recent Immunization Updates

Jessica Schillinger, PharmD Candidate 2019
University of Maryland School of Pharmacy

Deanna Tran, PharmD, BCACP
Assistant Professor, Department of Pharmacy Practice and Science, University of Maryland School of Pharmacy

Introduction

Each year, the Centers for Disease Control and Prevention (CDC) updates recommendations on vaccinations for children aged 18 years and younger and for adults.[1,2] The Advisory Committee on Immunization Practices (ACIP) holds three meetings throughout the year to review scientific data and vote on vaccine recommendations. At the February 2018 ACIP meeting, the live attenuated influenza, hepatitis A, and human papillomavirus (HPV) vaccines were discussed amongst other topics. In October 2018, ACIP approved the 2019 immunization schedules and changes for children and adolescents aged 18 years or younger and adults aged 19 or older. These schedules were announced by the CDC's Morbidity and Mortality Weekly Report (MMWR) and published on the ACIP website and Annals of Internal Medicine in early February 2019. ACIP also discussed the following at the October 2018 meeting: an additional indication for the use of Hepatitis A vaccination, the use of the Anthrax vaccine for post-exposure prophylaxis, and reaffirmation of the seasonal influenza recommendations for the 2018–2019 season. In the most recent, February 2019 meeting, ACIP further discussed and adopted recommendations for the Anthrax vaccine in addition to discussing other topics.

Influenza

The 2017-2018 influenza season was severe, with over 100 hospitalizations per 100,000 people by the end of April, and 178 pediatric deaths, which surpassed previous seasons.[3,4] The season was predominated by the Influenza A subtype H3N2 virus. Influenza vaccinations reduced both outpatient visits and hospitalizations by 40% and 22% respectively.

The composition of the influenza vaccine for the 2019–2020 season is:[5]

- A/Brisbane/02/2018 (H1N1)pdm09-like virus — new strain this year
- A/Kansas/14/2017 (H3N2)-like virus — new strain this year
- B/Colorado/06/2017-like virus (Victoria lineage)
- B/Phuket/3073/2013 (Yamagata lineage) — quadrivalent only

The ACIP voted to resume the recommendation for the use of the quadrivalent live attenuated vaccine (LAIV4) based on evidence suggesting that the new H1N1 strain in the LAIV4 vaccine will result in improved effectiveness. This will be the first time since 2016 in which that LAIV has been recommended. It is important to note that there is no published effectiveness estimates for this new LAIV vaccine. The American Academy of Pediatric recommends the use of any licensed influenza vaccine, including the nasal spray, which was previously not recommended due to its lack of efficacy on a certain strain.[6]

Other changes for this year's flu season includes the following: intradermal influenza vaccine is no longer on the market, Fluarix Quadrivalent (IIV4, GSK) is now approved for ≥ 6 months old, Afluria Trivalent and Quadrivalent (Seqirus) is now approved for ≥ 5 years. This brings a total of five inactivated vaccines for 6-35 month-olds: Fluarix Quadrivalent (IIV, GSK), Afluria Trivalent and Quadrivalent (Seqirus), FluLaval Quadrivalent (IIV4, GSK), and Fluzone Quadrivalent (IIV4, Sanofi Pasteur).[7]

Hepatitis A

With recent multiple hepatitis A (HAV) outbreaks, it was ruled in the February 2018 ACIP meeting that hepatitis vaccines should be administered for post-exposure prophylaxis for all persons older than 12 months. Also, immune globulin (IG) may also be administered along with Hepatitis A vaccine to those older than 40 years old if it is available within 14 days of exposure. For infants 6–11 months traveling to endemic Hepatitis A areas, the vaccine should be administered, in addition to the adult population.

Data presented to the October 2018 ACIP meeting also resulted in an additional adult indication for the hepatitis A vaccine. Due to a 2–3 times higher odds of

acquiring hepatitis A infection, homeless individuals 18 years old and older are now included as an at-risk patient population and are recommended to receive the vaccine. According to the Housing and Urban Development 2018 Annual Homeless Assessment Report[9], 553,000 people are homeless on a single night, a 0.3% increase from 2017 and 10% since 2016. Their susceptibility is increased due to unsafe sanitary conditions, sexual practices, drug use, and crowding in transient housing options. The choice to include homeless individuals was made to reduce disease burden despite the potential of serious adverse events and limitations in determining the overall quality of evidence.

Groups at increased risk of HAV or severe HAV disease:[8]

- Travelers to endemic Hepatitis A area
- Men who have sex with men
- Users of injection and non-injection drugs
- Persons with clotting-factor disorders
- Persons who work with nonhuman primates
- Persons who anticipate close personal contact
- Persons with chronic liver disease
- Household members and other close personal contacts of adopted children newly arriving from countries with high or intermediate Hepatitis A endemicity
- Persons experiencing homelessness

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Human Papillomavirus (HPV)

In October 2018, the FDA approved an expanded indication for the use of the Gardasil 9 vaccine to include individuals, men and women, age 27 through 45.[10] ACIP is still discussing and plans on reviewing and potentially voting on this matter in the future.

Anthrax Vaccine

During the June 2018 meeting, ACIP advised policies that could be implemented to improve the efficiency of a mass anthrax vaccination campaign. One of the uses of the anthrax vaccine is for post-exposure prophylaxis in the event that *Bacillus anthracis* is used as a bioweapon. The vaccine is stockpiled by the US government in the case that there is a wide-area release of *B. anthracis* spores.

Data presented at this meeting resulted in the following three policy approvals to the anthrax vaccine: The administration of the vaccine, delivered subcutaneously, may now also be issued intramuscularly. It can be administered intramuscularly if the subcutaneous route presents clinical, operational, or logistical challenges that may delay or prevent effective vaccination. If there is an inadequate supply of anthrax vaccine available for post-exposure prophylaxis, either two full doses or three half-doses of anthrax vaccine absorbed (AVA) may be used to expand vaccine coverage.[11] Lastly, in immunocompetent adults ages 18–65 years old, antimicrobials given in conjunction with the anthrax vaccine may be discontinued after 42 days (as opposed to 60 days) after the first vaccine dose or two weeks after the last vaccine dose, whichever comes later.[12]

Additional data has emerged to suggest extending the booster dosing interval to greater than the recommended one year during the February 2019 ACIP meeting. The current recommendations for the dosing interval after schedule dosing is a booster at 12 and 18 months, then annually. The possibility of a three-year booster interval for those not at risk of anthrax exposure, such as military personnel and emergency or other responders, would reduce vaccination burden and adverse events[13]

Conclusion

Recent changes regarding vaccine recommendations and immunization practices originate from a variety of data from several studies and trials. Updated recommendations from ACIP's committee meetings help health care practitioners stay up-to-date with healthcare trends and new vaccination studies.

Abbreviations used: IIV, inactivated influenza vaccine; IIV4, quadrivalent inactivated influenza vaccine; RIV4; recombinant quadrivalent influenza vaccine; LAIV4, quadrivalent live attenuated influenza vaccine.

REFERENCES

1. CDC. Recommended immunization schedule for children and adolescents aged 18 years or younger, United States, 2018. www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf. Accessed January 16, 2019.
2. CDC. Recommended immunization schedule for adults aged 19 years or older, United States, 2018. www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf.. Accessed January 16, 2019.
3. CDC reported flu deaths in children exceeds seasonal high. June 8, 2018. www.cdc.gov/flu/spotlights/reported-flu-children- deaths.htm. Accessed January 16, 2019.
4. CDC. Fluview. Influenza-associated pediatric mortality. https://gis. cdc.gov/GRASP/Fluview/PedFluDeath.html. Accessed January 16, 2019.
5. CDC. Frequently Asked Flu Questions: 2019-2020 Influenza Season. https://www.cdc.gov/flu/season/flu-season-2019-2020.htm. Accessed April 25, 2019.
6. AAP Updates Vaccine Recommendations for 2019-2020 Flu Season. 14 Mar. 2019, www.aap.org/en-us/about-the-aap/aap-press-room/Pages/AAP-Updates-Vaccine-Recommendations-for-2019-2020-Flu-Season.aspx. Accessed April 25, 2019.
7. ACIP meeting focused on influenza, HPV, and much more ... APhA. https://www.pharmacist.com/article/acip-meeting-focused-influenza-hpv-and-much-more. March 6, 2018. Accessed January 28, 2019.
8. CDC. Hepatitis A Questions and Answers for Health Professionals. www cdc.gov/hepatitis/hav/havfaq.htm. Accessed April 25, 2019.
9. "AHAR Reports." HUD Exchange, Dec. 2018, www.hudexchange.info/homelessness-assistance/ahar/. Accessed January 28, 2019.
10. Commissioner, Office of the. "FDA Approves Expanded Use of Gardasil 9 to Include Individuals 27 through 45 Years Old." 5 Oct. 2018, www.fda.gov/newsevents/newsroom/pressannouncements/ucm622715.htm. Accessed April 25, 2019.
11. Wright JG, Plikaytis BD, Rose CE, et al. Effect of reduced dose schedules and intramuscular injection of anthrax vaccine adsorbed on immunological response and safety profile: a randomized trial. Vaccine. 2014 Feb 12;32(8):1019-28.
12. Bernstein DI, Jackson L, Patel SM, et al. Immunogenicity and safety of four different dosing regimens of anthrax vaccine adsorbed for post-exposure prophylaxis for anthrax in adults. Vaccine. 2014;32(47):6284-93.
13. CDC. ACIP Vaccine Recommendations, Schedules, and GRADE. https://www.cdc.gov/vaccines/acip/recommendations.html. Accessed April 25, 2019.

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Continuing Ed

The Role of a Pharmacist in Gender Affirming Care

Christine Dimaculangan, PharmD
PGY-2 Ambulatory Care Pharmacy Resident, University of Maryland School of Pharmacy (2018-2019)

Learning Objectives

After having read this article, the pharmacist and/or pharmacy technician will be able to:

- **Describe** hormone pharmacotherapy options for transgender patients seeking gender affirming care
- **Discuss** factors taken into consideration prior to the initiation of gender affirming care
- **Counsel** patients on common adverse events and administration instructions associated with hormone therapy in the setting of gender affirming care
- **Identify** barriers of gender affirming care and **discuss** how to combat barriers of gender affirming care in the transgender patient population
- **Identify** the role of a pharmacist in an interprofessional transgender care clinic
- **List** resources for pharmacists who may be entering a new transgender care clinic

The Impact of the Transgender Population

Based on state-level surveys from California and Massachusetts in 2011, it was estimated that 0.3% of the U.S. adult population or 700,000 adults identified as transgender. This is recognized to likely be an underestimation, as individuals who identify as transgender may not do so publicly. National surveys such as the American Community Survey and the National Health Interview Survey do not measure the amount of people whose gender identity does not correlate with their sex assigned at birth. A 2016 study by the Williams Institute found that this population doubled to 0.6% of the United States population, equating to an estimated 1.4 million adults. In Maryland, there are an estimated 22,300 adults, or 0.49% of the state population, who identify as transgender, most of whom are between the ages of 25-64 years.[1]

Representation and identification of the transgender patient population is continually growing. "Gender dysphoria" is the official terminology used by the American Psychiatry Association, which is defined as a conflict between a person's physical/assigned gender and the gender with which they identify [as seen in Table 1]. Adult patients are diagnosed with gender dysphoria if they present with significant distress or problems functioning for at least 6 months and are identified by at least 2 of the following:

- Marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics
- A strong desire to be rid of one's primary/secondary sex characteristics
- A strong desire for the primary/secondary sex characteristics of the other gender
- A strong desire to be the other gender
- A strong desire to be treated as the other gender
- A strong conviction that one has the typical feelings/reactions of the other gender.

There are different degrees of gender dysphoria; certain individuals would like to be acknowledged as a woman or man and other individuals may be interested in more intense therapy or gender reassignment surgery.[2] Along with the degree of gender dysphoria, it is also important to consider additional existing cardiovascular (CV) comorbidities (e.g. previous CV events, present smoker, hypertension, diabetes) that may be present prior to an individual identifying as transgender. These factors may direct therapeutic decisions on the appropriateness and safety of initiating gender affirming care. Regardless of the degree of gender dysphoria an individual identifies as, it is important to acknowledge and weigh the person's wants and needs. This article will highlight the role of pharmacists and pharmacy technicians in providing patient care to this specific population.

Table 1: Terminology (Referenced from the Center of Excellence for Transgender Health):[4]	
Term	**Definition**
Sex	Historically has referred to the sex assigned at birth
Gender/Gender Identity	A person's internal sense of self
Gender expression	The outward manner in which an individual expresses or displays their gender
Transgender man or woman	Gender identity that differs from the sex that was assigned from birth
Cisgender	Gender identity that is the same as the sex that was assigned from birth

Initiating Hormone Therapy for Gender Affirming Care[3]

Historically, different criteria have been used to assess readiness for hormone therapy initiation for transgender individuals. In some cases, a mental health professional who has evaluated the person identifying as a transgender man or woman will send a referral letter to the provider to indicate a person's readiness to initiate therapy. In other cases, providers initiate interventions based on the person's informed consent. The World Professional Association for Transgender Health (WPATH) Standards of Care recognizes both ways of initiating therapy. WPATH notes certain patient-specific factors that help identify whether it is appropriate to initiate hormone therapy for gender affirming care. These factors include:

- Persistent, well-documented gender dysphoria
- Capacity to make a fully informed decision and to consent for treatment
- Age of majority in a given country
- If significant medical or mental health concerns are present, they must be reasonably well-controlled.[3]

The Center of Excellence for Transgender Health, affiliated with the University of California, San Francisco, also recognizes that providers who "feel comfortable making the respective diagnosis and starting treatment" should be able to initiate patients on gender affirming care, barring any existing risk factors (e.g. cardiovascular risk factors). Listed qualified prescribers for gender affirming care, are primary care physicians, obstetricians-gynecologists, endocrinologists, advanced practice nurses, and physician assistants.[6] There are four options for gender affirming care:

- Changes in gender expression and role
- Initiation of hormone therapy to feminize or masculinize body
- Surgery to change sex characteristics, and/or
- Psychotherapy

The remainder of this article will highlight hormone therapies commonly used for gender affirming care. Currently no pharmacologic agents have received approval from the Food and Drug Administration (FDA) for the indication of gender affirming care. This article will therefore include a discussion of off-label use for medications initially approved for other indications including menopause, contraception, hirsutism, male patterned baldness, prostatism, or abnormal uterine bleeding. For any patient who may be started on hormone therapy for gender affirming care, it is recommended that hormone levels (e.g., estradiol, total testosterone, and sex hormone binding globulin) are monitored throughout treatment to ensure that the patient has adequate sex hormones present. The guidelines set forth by Centers of Excellence for Transgender Care for gender affirming care do not recommend a specific target range for these hormones in the setting of gender transition. These guidelines acknowledge that individual institutions may have differing reference ranges for certain labs and encourages providers to reference these differences when making their decision on how to titrate treatment on a patient-specific level. Additionally, estradiol should be monitored regularly and to maintain levels that reflect the mid-cycle range for cisgender women, which helps to minimize adverse events from therapy. Patients with higher estrogen levels may have results indicating androgen suppression, but this may not result in additional breast development or other evidence of feminization.

Male-to-Female Transition[4]

Goals of therapy for patients transitioning from male to female are to develop female secondary sex characteristics and to suppress or minimize male secondary sex characteristics. The general approach to therapy is to combine estrogen with an androgen blocker or, at times, add a progestogen. The most common estrogen that is used in this patient population is 17-beta estradiol, a "bioidentical hormone", defined as being chemically equivalent to that produced by a human ovary. This formulation has less of an impact on the synthesis of hepatic proteins than ethinyl estradiol, which may yield a better metabolic profile.[5] Similar to estrogen replacement therapy, multiple routes of administration are available, including oral, transdermal, and injectable. Examples of hormone preparations used in the setting of gender affirming care can be referenced in table 2 (see next page)[4]. Adverse effects associated with estrogen therapy include migraines, mood swings, hot flashes, and weight gain. Also, serious concerns associated with the use of hormone therapy include cardiovascular and thrombotic risks. Given the limited information

available on actual risk, it is important to screen for cardiovascular and thrombotic risk factors, such as comorbidities (e.g. diabetes, hypertension, and hyperlipidemia), history of or current cigarette smoking, and age. Similar to estrogen therapy, there is limited to no evidence on progestogen use in gender affirming care. Patients who have been on progestogens in this setting have noticed improved breast development, mood, and libido with its use. Conversely, other sources report worsening mood. As mentioned previously, two treatment options in the progestogen class, which can be added include medroxyprogesterone acetate and micronized progesterone.

Many patients also start on anti-androgenic therapy to enhance the feminizing effects derived from estrogen therapy. Spironolactone and the 5-alpha reductase inhibitors (e.g. dutasteride and finasteride) are the primary agents used for anti-androgenic therapy. Anti-androgens are associated with breast development and reduced masculinization. Upon review of the literature, the use of spironolactone was exclusively mentioned in the setting of gender affirming care; eplerenone use was not discussed. Anti-androgenic effects from spironolactone are typically seen with increased doses. Doses of spironolactone up to 400 mg/day have shown no negative effect when used for hair loss in women.[4] Common adverse events associated with the use of spironolactone are typically self-limiting and may include polyuria, polydipsia, or orthostasis. Another serious, but rare effect of spironolactone, is the potential to develop hyperkalemia. Guidelines suggest obtaining a baseline potassium level, along with additional lab values, as noted in table 3 (see next page)[4].

The other anti-androgenic agents used in gender affirming care are the 5-alpha reductase inhibitors. The 5-alpha reductase inhibitors convert testosterone to the potent

Table 2: Recommended Hormone Preparations and Dosing (Adapted from the Centers of Excellence for Transgender Health):[4]

Therapy	Initial (low)**	Initial	Maximum	Additional comments
Estrogen				
Estradiol oral/ sublingual	1 mg/day	2-4 mg/ day	8 mg/day	If >2 mg recommend divided BID dosing
Estradiol transdermal patch* **	50 mcg	100 mcg	100-400 mcg	Max single patch dose is 100 mcg, and administration of 2 patches may be complex for some patients. It is NOT permissible to cut patches.
Estradiol valerate IM	<20 mg Q 2 weeks	20 mg Q 2 weeks	40 mg Q 2 weeks	May divide dose into weekly injections for cyclical symptoms*
Estradiol cypionate IM	<2 mg Q 2 weeks	2 mg Q 2 weeks	5 mg Q 2 weeks	May divide dose into weekly injections for cyclical symptoms*
Androgen Blockers				
Spironolactone oral	**25 mg daily**	**50 mg BID**	**200 mg BID**	
Finasteride oral	**1 mg daily**		**5 mg daily**	
Dutasteride oral	**0.5 mg daily**			
Progestogen				
Medroxyprogesterone acetate oral	**2.5 mg QHS**		**5-10 mg QHS**	
Micronized progesterone oral	**100-200 mg QHS**			

*Cyclical symptoms: also referred to vasomotor symptoms which include hot flashes and additional cognitive and mood symptoms.

**Low: Initial dosing is what is recommended, the lower initial dose is recommended for patients who desire starting a lower dose or those who may have existing medical conditions that would warrant lower initial dosing

***Frequency not listed per guidelines, may be dependent on provider of patient

anti-androgen dihydrotestosterone. These medications are considered an alternative for patients who have contraindications or intolerance to spironolactone and should not be used in combination with spironolactone. Adverse effects of 5-alpha reductase inhibitors include hair loss, decreased libido, impotence, and ejaculatory disorders.

Female-to-Male Transition[4]

The goal of therapy for transgender men (females transitioning into a male) undergoing hormone therapy is to develop male secondary sex characteristics (e.g. the development of facial hair, deepening of the voice, and redistribution of facial and body fat). The mainstay of treatment for masculinizing gender affirming care is testosterone. All testosterone products approved for marketing in the United States are bioidentical to the testosterone naturally secreted by the human testicle. Testosterone is available as both subcutaneous and intramuscular injections as well as topical formulations. Available formulations in the setting of gender affirming care can be referenced in table 4 (see page 20)[4]. Testosterone therapy is approved for use in males with low androgen levels. In the case of individuals seeking to transition from female to male, baseline testosterone levels are little to none. For instance, cisgender men typically have testosterone levels of 280 to 1,100 ng/dL, while cisgender women have levels typically between 15 and 70 ng/dL. Transgender men will likely require higher doses of testosterone in the setting of gender affirming care. Recommended laboratory monitoring (from the Centers of Excellence for Transgender Health) can be referenced in table 5 (see page 21)[4].

Addressing Cultural Competency in the Transgender Patient Population[7]

The Transgender Law Center created a document outlining different ways for healthcare providers to improve services and better acknowledge the transgender patients we serve. With the goals of improving transgender patient care and providing positive patient outcomes, they recommend:

1. Welcome transgender people by displaying "transgender-positive phrases" (e.g. preferred pronouns), advertising inclusive services, and updating intake forms at your site.
2. Treat transgender patients with the same respect that you would want to receive.
3. Be sure to use pronouns that coincide with your patient's gender identity.
4. If you are unsure about the gender identity the person prefers, politely ask for clarification.
5. Establish a policy for addressing discriminatory comments and/or behavior at your site.
6. Remember to focus on questions involving patient care and not asking questions out of curiosity.
7. Always ask permission before using a patient encounter as teaching opportunities for staff members or trainees. Training may not be appropriate in all scenarios, or acceptable to all patients.
8. It is inappropriate to ask a patient of their genital status, unless it is directly relating to the care you are providing.
9. It is especially important not to disclose a patient's transgender

Table 3: Recommended Laboratory Monitoring for Feminizing Hormone Therapy (Adapted from the Centers of Excellence for Transgender Health):[4]

Test	Comments	Baseline*	3 mos**	6 mos**	12 mos**	Yearly	PRN
BUN/Cr/K+	**Only** if spironolactone is used	✓	✓	✓	✓	✓	✓
Lipids	No evidence to support; **use** clinician discretion	Reference from USPSTF guidelines					✓
A1c or glucose	No evidence to support; **use** clinician discretion	Reference from USPSTF guidelines					
Estradiol			✓	✓			✓
Total testosterone			✓	✓	✓		✓
Sex hormone binding globulin			✓	✓	✓		✓
Albumin			✓	✓	✓		✓
Prolactin	**Only** if patients present with symptoms of prolactinoma						✓

*Of note, these timelines are not evidence-based and are recommendations. Reference ranges and timeline for monitoring are based on non-transgender patients.

**This frequency in the first year of therapy only, frequency after the first year is yearly.

status to anyone who does not explicitly need this information to provide care.

10. Be aware and educated about health care issues that pertain to the transgender patient population.

Barriers in Gender Affirming Care[8]

In an article by Puckett and colleagues, barriers to gender affirming care include: financial, medical care, mental health, quality, and timing of care. Financial concerns are the most common reason people who identify as transgender do not seek gender affirming medical care. Financial concerns can include cost of hormone therapy, lab work, primary care visits, and/or mental health visits (e.g. psychiatrist, therapist). Some people have postponed important life events such as pursuing graduate or post-graduate education to pay for healthcare costs associated with gender affirming care. Transgender individuals have endorsed concerns for obtaining employment, likely stemming from fear of discrimination within the workforce, which also represents a financial barrier to care. People identifying as transgender may not seek medical care for fear of discrimination from their peers. There are reports of fear and anxiety surrounding interactions with peers and people within their community. Age and timing of care is a barrier to access, as younger patients and adolescents will require parent permission in order to move forward with gender affirming care. Limited availability and overall quality of care are other concerns. Many transgender people have expressed their fear of insufficient facilities to address specific concerns and limited providers who specialize in this field of medicine. System or site wide policies can also present barriers including the terminology available on forms (e.g. no option for non-binary gender identities, spaces to indicate 'preferred' as well as 'legal' names, etc.), systems communicating these preferences to

Table 4: Recommended Hormone Preparations and Dosing for Masculinizing Hormone Therapy (Adapted from the Centers of Excellence for Transgender Health):[4]

Therapy	Initial (low dose)	Initial (typical)	Maximum (typical)	Comment
Testosterone cypionate	20 mg/week IM/SQ	50 mg/week IM/SQ	100 mg/week IM/SQ	For q 2 weeks dosing, double each dose
Testosterone enthanate	20 mg/week IM/SQ	50 mg/week IM/SQ	100 mg/week IM/SQ	" "
Testosterone topical gel 1%	12.5-25 mg Q AM	50 mg Q AM	100 mg Q AM	Pump or packet form; to be applied to right and left upper arms/ shoulders and/or right/left abdomen.
Testosterone topical gel 1.62%	20.25mg Q AM	40.5 – 60.75 mg Q AM	103.25 mg Q AM	" "
Testosterone patch	1-2 mg Q PM	4 mg Q PM	8 mg Q PM	Available in 2 mg or 4 mg sizes, may cut patch if lower doses are desired; to be applied on the back, abdomen, upper arms, or thighs only
Testosterone cream*	10 mg	50 mg	100 mg	
Testosterone axillary gel 2%	30 mg Q AM	60 mg Q AM	90 – 120 mg Q AM	Available as pump only ; one pump = 30 mg
Testosterone undecanoate	N/A	75 mg IM, repeat in 4 weeks, then every 10 weeks ongoing	N/A	Requires participation in manufacturer monitored program

*Frequency not listed per guidelines, may be dependent on provider of patient

all staff members, and availability of facilities like single-use bathrooms. Even providers who are familiar with and invest their time in providing gender affirming care, they may still lack experience. The knowledge gaps in the literature and guidance for care for this patient population contribute to these barriers and fuels the need for additional research to be done in this field.

The Role of Pharmacists and Pharmacy Technicians in Transgender Care[9,10,11,12,13]

With an increasing number of individuals identifying as transgender, the role of the

Table 5: Recommended Laboratory Monitoring for Masculinizing Hormone Therapy (Adapted from the Centers of Excellence for Transgender Health):[4]

Lipids	Comments	Baseline	3 mos**	6 mos**	12 mos**	Yearly	PRN
A1c or fasting glucose	No evidence to support monitoring this, use clinician discretion	Based on USPSTF guidelines					✓
Estradiol	No evidence to support monitoring this, use clinician discretion	Based on USPSTF guidelines					✓
Total testosterone							✓
SHBG*			✓	✓	✓		✓
Albumin			✓	✓	✓		✓
Hemoglobin & Hematocrit		✓	✓	✓	✓		✓

*SHBG: Sex Hormone Binding Globulin

This frequency in the first year of therapy **only, frequency after the first year is **yearly**.

Table 6: Available Resources in Guidance for Gender Affirming Care:

Link	Resource/Citation
Available Guidelines	
The World Professional Association for Transgender Health	World Professional Association for Transgender Health. Standards of Care: Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People [Internet]. 2011. Available from: https://www.wpath.org/media/cms/Documents/SOC%20v7/SOC%20V7_English.pdf
The Center of Excellence for Transgender Health	Centers of Excellence for Transgender Health. Guidelines for the Primary Care of Transgender and Gender Nonbinary People [Internet]. 2016 June 17. Available from: http://transhealth.ucsf.edu/trans?page=guidelines-home
Additional Resources	
The National LGBT Health Education Center	www.lgbthealtheducation.org/
National Center for Transgender Equality	www.transequality.org
Mazzoni Center Philadelphia Trans Wellness Conference	www.mazzonicenter.org/trans-wellness
Models of Gender	www.confi.co/what-is-gender
Trauma-Informed Care	www.store.samhsa.gov/product/TIP-57-Trauma-Informed-Care-in-Behavioral-Health-Services/SMA14-4816
The 2015 US. Trans Survey	www.ustranssurvey.org/reports
Transgender Law Center	www.transgenderlawcenter.org/resources/health www.transgenderlawcenter.org/equalitymap
National Resource Banks of Gender Affirming Providers	www.radremedy.org/transcaresite.org www.glma.org

*Frequency not listed per guidelines, may be dependent on provider of patient

pharmacist in gender affirming care is also expanding. A description of the role of the pharmacist in a transgender health clinic in New Mexico, by Newsome and colleagues, reports on the services the pharmacist provides as part of a multidisciplinary team including a diabetes educator, an endocrinologist, a massage therapist, medical assistants, a nurse, a nurse practitioner, a nutritionist, and a psychiatrist. In this setting, the clinical pharmacist sees patients independently and provides the following services: discussing specific hormone therapies for gender affirming care (may vary based on existing collaborative practice agreements and established scope of practice), monitoring laboratory values, and identifying risk reduction strategies. Risk reduction strategies include management of cardiovascular risk factors such as diabetes, dyslipidemia, nicotine dependence, and obesity. The pharmacist's role in this clinic has expanded their scope of practice and broadened the population of patients they serve.

Pharmacists and pharmacy technicians can play a significant role in the care of patients who identify as transgender even if they do not practice in specialized clinical settings. Through better incorporation of preferred pronouns in the community pharmacy setting, assisting with insurance coverage and/or obtaining prior authorizations for hormone therapy, and implementation of systemic changes to appropriately address the needs of transgender individuals, pharmacists can improve the experience and reduce barriers to care for this underserved population. Table 6 (see below) provides a list of available resources to provide education and information for providers and healthcare professionals working in this field of interest.

REFERENCES

1. Flores AR, et al. How many adults identify as transgender in the United States [Internet]? The Williams Institute. 2016 June. Available from: https://williamsinstitute.law.ucla.edu/wp-content/uploads/How-Many-Adults-Identify-as-Transgender-in-the-United-States.pdf
2. American Psychiatry Association. What is gender dysphoria? [Internet]. 2018. Available from: https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria
3. World Professional Association for Transgender Health. Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People [Internet]. 2011. Available from: https://www.wpath.org/media/cms/Documents/SOC%20v7/SOC%20V7_English.pdf
4. Centers of Excellence for Transgender Health, Department of Family and Community Medicine, University of California San Francisco. Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People;2nd edition. Deutsch MB, ed. June 2016. Available at www.transhealth.ucsf.edu/guidelines.
5. Tremollieres F. Oral combined contraception: is there any difference between ethinyl estradiol and estradiol? Gynecol Obstet Fertil. 2012 Feb;40(2): ;109-15. Doi:10.1016/j.gyobfe.2011.10.009. Epub 2012 Jan 12.
6. Deutsch MB, Feldman JL. Updated recommendations from the world professional association for transgender health standards of care. Am Fam Physician. 2013 Jan 15;87(2):89-93.
7. Transgender Law Center. 10 Tips for Working with Transgender Patients: An Information and Resource Publication for Health Care Providers [Internet]. 2016. Available from: www.transgenderlawcenter.org.
8. Puckett JA, et al. Barriers to Gender-Affirming Care for Transgender and Gender Nonconforming Individuals. Sex Res Soc Policy. DOI 10.1007/s13178-017-0295-8.
9. Brennan A, Barnsteiner J, Siantz ML, Cotter VT, Everett J. Lesbian, gay, bisexual, transgendered, or intersexed content for nursing curricula. J Prof Nurs. 2012;28(2):96-104. 15.
10. Maxwell E, et al. Discrepancies in Lesbian, Gay, Bisexual, and Transgender Patient Care and How Pharmacists Can Support and Evolved Practice. American Journal of Pharmaceutical Education 2017; 81(7). Article 6181.
11. Kelley L, Chou CL, Dibble SL, Robertson PA. A critical intervention in lesbian, gay, bisexual, and transgender health: Knowledge and attitude outcomes among second-year medical students. Teaching and Learning in Medicine. 2009; 20(3), 248-253
12. Bonner, L. Pharmacists can be accessible, trusted providers for transgender patients. Pharmacy Today. March 2016.
13. Newsome C, Colip L, Sharon N, Conklin J. Incorporating a pharmacist into an interprofessional team providing transgender care under a medical home model. Am J Health-Syst Pharm. 2017; 74:13509. DOI 10.2146/ajhp160322.

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PATIENT CASE:
A Pharmacist's Role in Transgender Health

YL is a 37 y/o M presenting to your clinic who has recently identified as a transgender woman. Her preferred pronouns are "she/her/hers" and she is highly interested in gender affirming care to begin her transition from male to female. She has a past medical history of major depressive disorder (3 years) and GERD (1 year) but is otherwise healthy. Family history includes DM and HTN in both parents. Her medications include: alprazolam 0.25 mg 1 tablet PRN daily for anxiety, multivitamin 1 tablet daily, omeprazole 20 mg daily for GERD, and venlafaxine ER 75 mg 1 tablet daily for major depressive disorder (MDD). She has told a couple of her friends that she is transgender and is currently seeking hormone therapy to initiate her transition into becoming a female. She also discloses that she has not seen her psychiatrist in a few months due to her MDD being controlled. Due to this, she has had longer intervals between appointments with her psychiatrist.

Case Questions:

1) Which of the following risk factors do not need to be emphasized prior to the initiation of feminizing hormone therapy?

a. Risk of CVA

b. Risk of MI

c. Risk of VTE

d. Risk of developing GERD

2) Prior to initiating gender affirming care, YL will have the opportunity to meet with the clinic psychiatrist to review the overall process of gender affirming care. What will likely be included in this *initial* discussion prior to initiation of therapy?

a. Approval process for surgical intervention

b. Capacity to make a fully informed decision and to consent for treatment

c. Common adverse events prior to initiation of therapy

d. Significant cardiovascular health

3) YL returns for follow-up after initiating hormone therapy with estradiol oral tablet at 1 mg per day 3 months ago. Subjectively, she reports that she has been tolerating therapy well so far. What laboratory parameters should be monitored at this time?

a. Albumin

b. Lipids

c. Prolactin

d. SCr/BUN/K

4) YL has been on maintenance therapy for about 3 months at this time and the provider on her multidisciplinary team has decided to initiate anti-androgen therapy. All of the following are therapeutic options for YL at this time, except:

a. Dutasteride 0.5 mg daily

b. Finasteride 1 mg daily

c. Finasteride 5 mg daily

d. Spironolactone 25 mg

Answers on page 24

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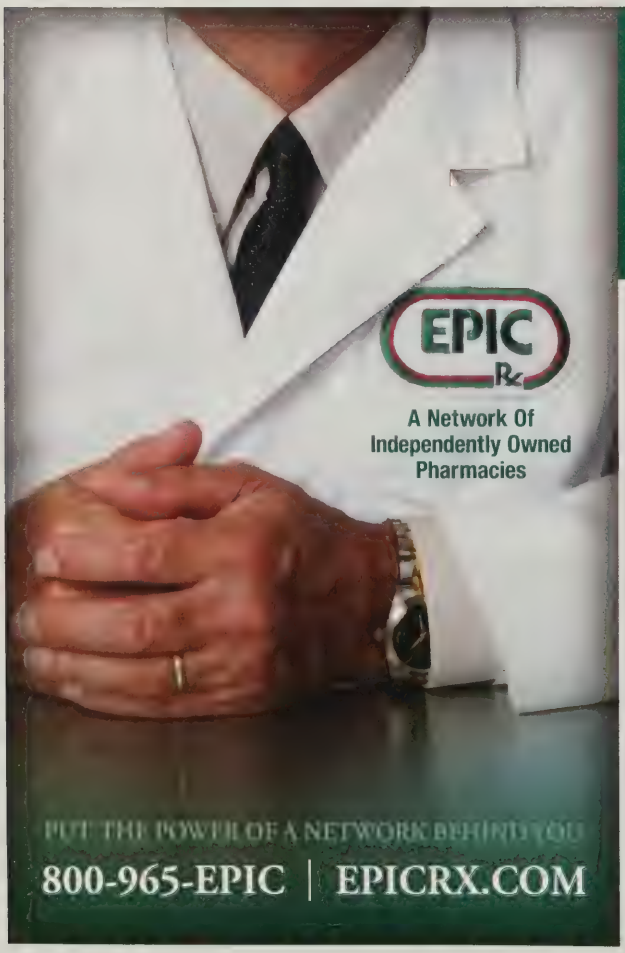
ANSWERS — PATIENT CASE: A Pharmacist's Role in Transgender Health

1) Answer: D. ***Rationale:*** Evidence is limited evidence for risks of initiating therapy in this specific patient population. There is no mention of increased risk of GERD in this patient population and (based on the patient's medication history), she is being adequately treated for this condition at this time. [Answer D is correct]. The remaining risk factors are of concern when initiating feminizing hormone therapy in the setting of gender affirming care due to evidence of increased risk of cardiovascular and thrombotic disorders with the use of estrogen for other indications.

2) **Answer: B.** ***Rationale:*** While the psychiatrist may discuss cardiovascular risk associated with the initiation of hormone therapy, this will more likely be addressed by the physician or pharmacist on the medical team [Answer D is incorrect]. Common adverse events are important to discuss when initiating therapy, but this role may be designated to the pharmacist on the team [Answer C is incorrect]. YL has disclosed she would like to initiate gender affirming care; surgical intervention may be a part of the conversation during hormone therapy, but is not a priority to discuss at this time [Answer A is incorrect]. A topic of discussion that would be a priority would be YL's ability to make a fully informed decision and the ability to consent for treatment, especially given YL's comorbidity of major depressive disorder [Answer B is correct]. Despite YL's MDD being stable at this time, this would still be a priority given the increased risk of mental health concerns in this patient population. Conversely, if YL's MDD was not adequately controlled, she may not be able to make a fully informed decision about her initiation of gender affirming care.

3) Answer A. ***Rationale:*** There is no evidence to support monitoring lipids during initiation of feminizing hormone therapy and is recommended (from WPATH guidelines) to monitor only as needed [Answer B is incorrect]. There is evidence for monitoring prolactin levels but only if patients present with symptoms of prolactinoma, at which time YL is not complaining of and this is recommended to be monitored as needed [Answer C is incorrect]. SCr, and K are not recommended to be monitored unless the patient is on spironolactone therapy, at which time patients should be monitored at baseline, 3 months, 6 months, and yearly after initiation of therapy [Answer D is incorrect]. Albumin is recommended to be monitored (after initiation of therapy) at 3 months, 6 months, 12 months, and yearly thereafter [Answer A is correct] for all feminizing hormone therapy.

4) Answer B. ***Rationale:*** Dutasteride can be an initial recommended agent for anti-androgenic therapy and 0.5 mg is a recommended initial dose [Answer A is incorrect]. Finasteride 1 mg is the recommended initial dose and finasteride [Answer B is incorrect] 5 mg daily is the maximum dose. Since finasteride 1 mg is the recommended initial dose, finasteride 5 mg would not be recommended for initiation of therapy [Answer C is correct]. Spironolactone 25 mg daily is a recommended initial dose of anti-androgenic therapy [Answer D is incorrect].



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Executive Director's Message

I was introduced to Formula 1 racing this summer. Honestly, at first, I didn't get it at all, but I learned that there's more to it than mindlessly driving around a track. It's about technique, calculated risk and finesse. Now, I'm kind of obsessed! In my research about F1, I read about Mario Andretti, one of the most successful American racers in history. This quote from him resonated with me as I thought about the conclusion of our Annual Convention and moving into the next MPhA year.

"Desire is the key to motivation, but it's determination and commitment to an unrelenting pursuit of your goal—a commitment to excellence—that will enable you to attain the success you seek." —Mario Andretti

We celebrated excellence in pharmacy practice at our Annual Awards luncheon. The recipients all demonstrated a level of achievement that has helped to advance our Maryland pharmacy community -- mentorship, advocacy, interprofessional engagement, public service and education. Our awardees did not pursue their goals for "success" or "recognition." They were determined and committed to pursuing excellence in their profession and that is what has shown through. Their community of peers saw it and recognized it. I thank all our awardees for the work they have put in to support MPhA and the communities they serve in both their professional and personal lives. We are grateful for their commitment to excellence.

The staff and leadership of MPhA are also motivated to continue to build your organization and promote pharmacy in Maryland for what YOU desire it to be. In the coming year we'll be taking some calculated risks to achieve our organizational goals. The Annual Convention gets us reenergized and more determined than ever to work with you and our stakeholders to push and build toward excellence!

Thank you for your continued support of MPhA!

Be well,

Aliyah N. Horton, CAE
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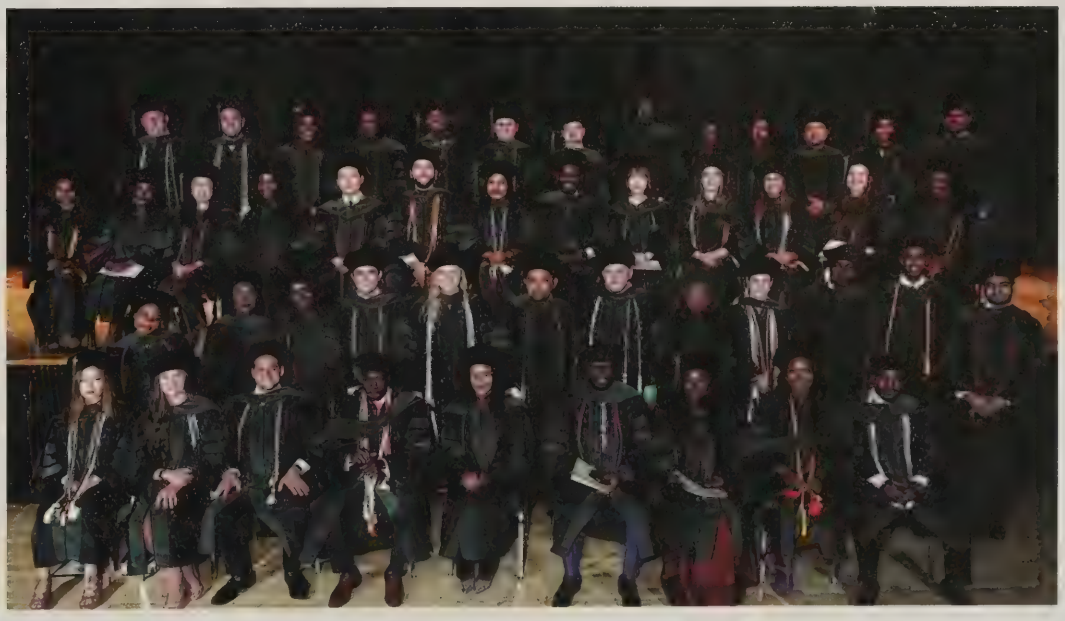

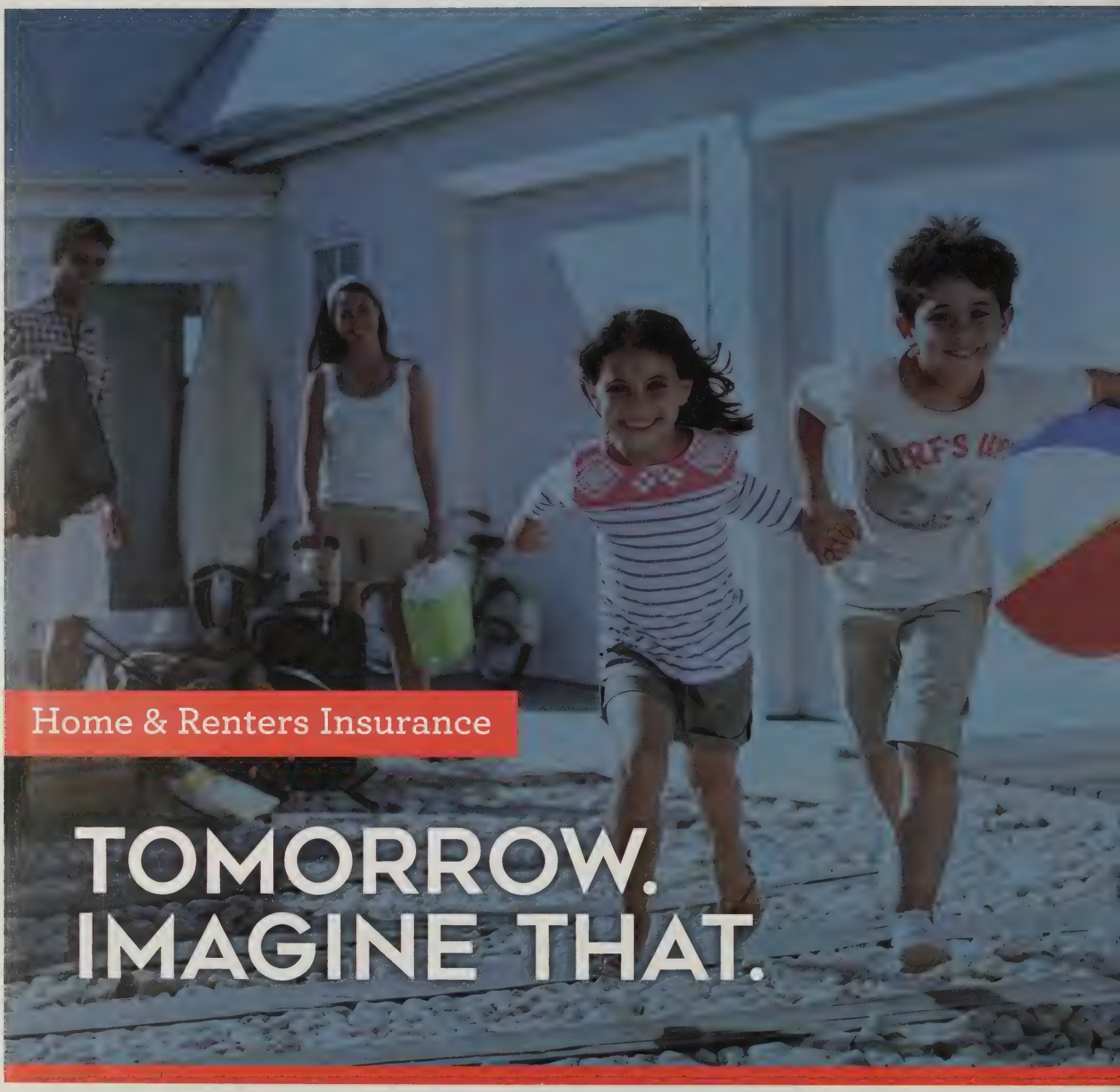

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MPhA Launches New Membership Structure

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President's Pad

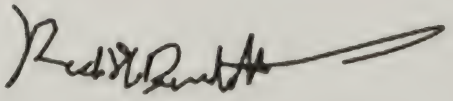
Happy American Pharmacists Month!

We welcome you back to the start of a new year with MPhA with some exciting happenings and great member value. While we didn't have meetings in July and August, a lot has been going on in the background. One of the biggest pieces of news and excitement is the change to our membership structure; this change allows for you to choose what you want from your membership. Do you want to be informed, engaged or connected? This is an opportunity for MPhA to really grow its membership and to better serve pharmacy in the state of Maryland. Another new offering is the MPhA podcast, The PharmCast, discussing important topics in pharmacy. Of course, advocacy never stops, and we have been working with many stakeholders on Long Acting Injectables and have taken on another project related to opioid overdose education. We have a large group of members involved in kick starting activities for the different committees this fall and you should be hearing about those activities soon!

At the September MPhA Board meeting I called on the Board, just as I call on you now, to remember that **WE ARE MPhA**. The association is made up of us, and it needs us to do its work. I call on you to provide outreach regarding membership as well as activities. There is no longer ANY financial barrier to membership – all are welcome and all should become members. Please reach out to your friends, colleagues, and even new pharmacists and technicians and invite them to join the MPhA family.

As I reflect on being a pharmacist during American Pharmacists Month, I am constantly in awe of the good that we can do. All pharmacists have the opportunity to make a difference for a patient. Take a moment to reflect on the impact you have had on your patients and consider the countless others you unknowingly made. Pharmacy is hard; you must reap the rewards in order to make it through the hard times. I teach my students to save a life every day. Each recommendation you make, no matter how small or insignificant it may be to you, may save someone's life. I encourage you to remember that during each hard day you work – you are making lives better for your patients.

If you have any new or innovative ideas on events, ways to be engaged, or things that MPhA can do to meet your needs and connect you with other members, please let any member of the Board of Trustees or me know. **WE** ARE MPhA and **WE** have to make MPhA what we want it to be.



Richard DeBenedetto,
PharmD, MS, AAHIVP

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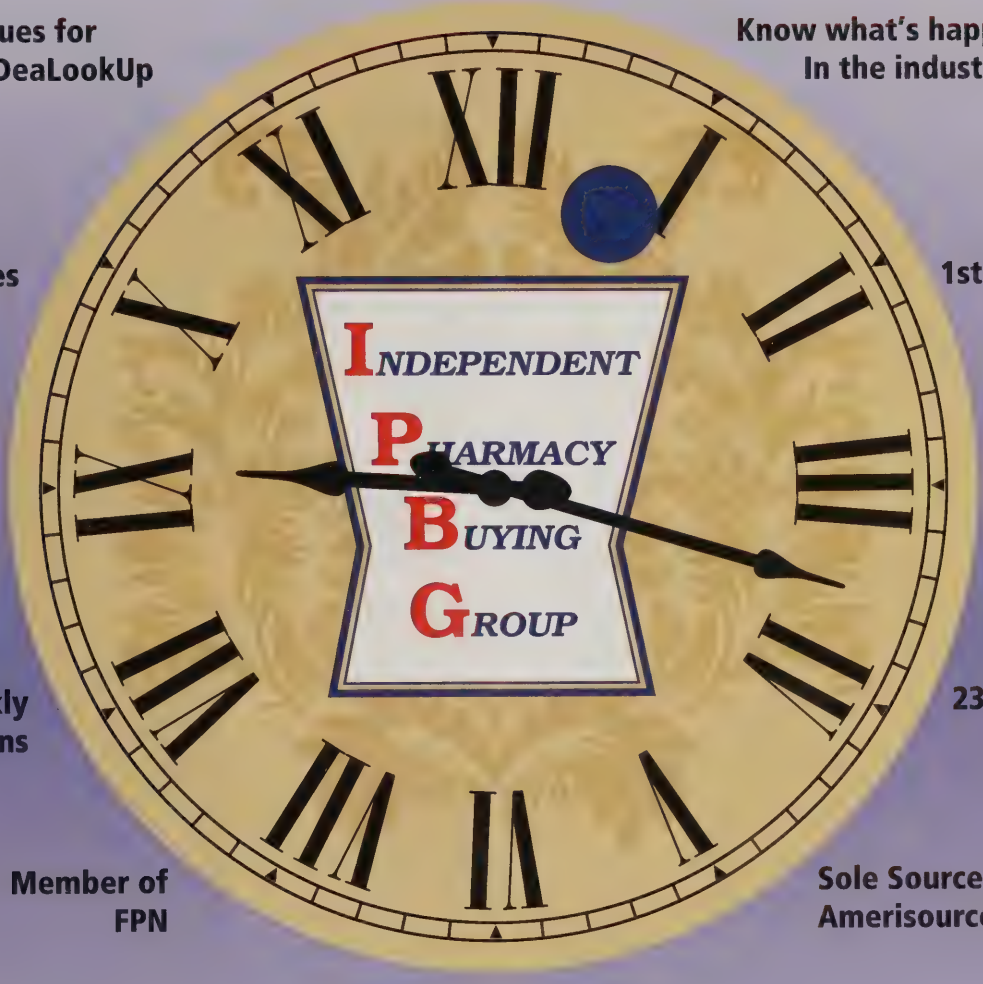

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Member Mentions & News You Can Use

Marci Strauss Joins MPhA Board of Trustees

MPhA Board of Trustees is pleased to announce that it has appointed Marci Strauss, PharmD to complete the unfinished trustee term of newly-installed Vice President Kerry Cormier. Dr. Strauss currently serves as Manager of Clinical Programs at EPIC Pharmacies, Inc. Welcome, Marci!

MPhA Past President Joins Notre Dame

Former MPhA President, Matthew Shimoda has joined Notre Dame of Maryland University School of Pharmacy as Assistant Dean of Student Affairs. Congratulations Matthew!

Bresette Briefs Governor's Opioid Council

MPhA Member James Bresette briefed the Executive Director of the Governor's Opioid Operations Command Center and the Interagency Heroin and Opioid Coordinating Council quarterly meeting this past summer. Preliminary numbers suggest that opioid-related deaths in Maryland have gone down in the first quarter of 2019. Officials say this decrease may be due in part to the work of local universities, like the University of Maryland Eastern Shore, and groups like RALI Maryland and its interactive trailer.

"We know we are making a difference. We've seen it. We've heard the stories of people in the community," said Dr. Bresette.

Brandt Receives National Award for Leadership in Geriatrics Education

Nicole Brandt, PharmD, MBA, BCPP, BCGP, FASCP has been named the 2019 recipient of the American Geriatrics Society's (AGS) Dennis W. Jahnigen Memorial Award. This annual award recognizes AGS members who have provided leadership to train students in geriatrics and significantly contributed to the progress of geriatrics education in health profession schools. She is the first pharmacist to be honored with the award.

Honkofsky Recognized in Baltimore Sun

MPhA member and retired pharmacist Arnie Honkofsky of Owing Mills was recently featured in the Baltimore Sun for his work advocating for Death with Dignity legislation. Eight states, plus DC, currently have death with dignity legislation but Maryland's proposed legislation was defeated earlier this year.

MPhA Hosts Flu Shot Clinic

MPhA was happy to welcome our neighbors in to our headquarters for their annual flu shot. Thank you to Rite Aid for supporting this community effort once again this year!

MPhA Launches *The PharmCast*

The PharmCast is a podcast hosted by MPhA Executive Director Aliyah Horton. In her role she interacts with pharmacists, stakeholders, students, leaders and innovators from around the country. *The PharmCast* is a great opportunity to share that information and experience. The conversations are about policy, people and the profession. It's one way MPhA is fulfilling its mission to strengthen the profession of pharmacy, advocate for pharmacists and promote excellence in pharmacy practice. The goal is for listeners to leave *The PharmCast* informed, engaged and connected to the broader pharmacy community. Visit https://anchor.fm/ThePharmcast to listen!

Continued on page 22

MPhA
MARYLAND PHARMACISTS ASSOCIATION

New Membership Structure

Who said you can't have it your way?

MPhA is giving you the opportunity to renew your 2020 membership based on what you want and value.

HERE'S WHAT'S NEW

Pharmacists will no longer be tied to membership categories based on industry tenure or practice setting. We now have individual membership categories that provide you what you want from MPhA — to be **informed, engaged or connected**. Renewal for 2020 membership is now available, along with other new member services! We are excited about these new opportunities for outreach and engagement with you.

WHY THE NEW MEMBERSHIP CATEGORIES?

The membership categories were revised to:

- Increase MPhA's opportunity to share information with the broader Maryland pharmacy community
- Support more engagement and utilization of MPhA programs, products and resources
- Strengthen our advocacy efforts on behalf of the practice and profession
- Facilitate more networking and connectedness across the state

INFORMED, ENGAGED and **CONNECTED** members of the pharmacy community provide MPhA the power to continue to fulfill our mission to promote excellence in pharmacy practice, strengthen the profession of pharmacy and advocate for all Maryland pharmacists!

DO YOU WANT TO BE ...

INFORMED

This will be a fantastic opportunity to build your network within the pharmacy community. The INFORMED members will receive the Monday Message, Advocacy Alerts and notices about MPhA events and products. *Informed members will not have voting rights or receive member discounts.*

Dues: FREE

ENGAGED

This level will take your engagement up a notch. The category includes all of the benefits from the Informed level plus voting rights, *Maryland Pharmacist* digital Journal, MPhA partner benefits and education discounts (at least $250 in savings).

Dues: $125

CONNECTED

This level provides all the benefits MPhA has to offer and recognition as being fully connected to your Maryland pharmacy community. Benefits include all the above plus continued delivery of the print Journal, member discounts on ALL products and services, access to invitation-only events and more. In addition, the dues will include the membership fee for the MPhA Foundation.

Dues: $250 *(two memberships in one!)*

ASSOCIATE

Associate benefits remain the same with continued delivery of the print journal.

Dues: $250

TECHNICIAN

Technician benefits remain the same with the journal provided in digital format.

Dues: $25

STUDENT

Student benefits remain the same with the journal being provided in digital format.

Dues: $10

For more information about group (five or more members) and corporate partner memberships, please contact Lauren Williams at lauren.williams@mdpha.com.

Editorial

The Tech-Check-Tech Program in the Community Pharmacy Setting

John Lee, PharmD, and Deanna Tran, PharmD, BCACP, Assistant Professor
Department of Pharmacy Practice and Science, University of Maryland School of Pharmacy

Disclosure: Nothing to disclose

According to nationally collected data, pharmacists are working in high-stress environments with poor job satisfaction.[1] A possible solution to alleviating pharmacists' stress is to increase the scope of pharmacy technicians. One such practice, termed tech-check-tech (TCT), has gained favor amongst health-system pharmacists as a significant potential change to reform the pharmacy practice model. TCT refers to an accuracy checking technician initiative where technicians would be able to perform the final product verification on any filled prescription. However, opinions among community-based pharmacists differ from those in health-systems as the working environments for both pharmacists and pharmacy technicians are not easily comparable. Available data supports the notion that advancing the technician's role through TCT could decrease pharmacists' burden and enhance patient safety by allowing the pharmacist to more readily focus on clinical services in hospital settings.[2] This article will explore the thoughts and concerns towards TCT, focusing on the community-based pharmacy setting.

One of the concerns many have on the suggestion of TCT is whether patients' safety may be jeopardized by delegating final prescription verification to a technician. To help address this, a study by Fleagle et. al was conducted at an outpatient community pharmacy where a TCT technician verified a dose a pharmacist had previously performed a check on for clinical appropriateness and reviewed for transcription into the pharmacy dispensing software. Over a 4-week data collection period, technicians were as accurate as pharmacists in checking final dispensed prescriptions, at rates of 99.95% [95% CI 99.89%-99.99%] versus 99.74% [95% CI 99.61%-99.87%] of pharmacists, indicating no statistical differences in the accuracy of checking the dispensed prescriptions between technicians and pharmacists.[3] Additionally, the study found that the incorporation of a TCT technician saved the pharmacist time that was equivalent to about 23 days per year. The time saved was calculated through recorded measurements of prescription checking times. Thus, the study concluded that TCT programs were practical for community settings, patient safety was not compromised, and TCT may be a practical way for the pharmacist to focus on advanced patient care activities. These conclusions were supported and reciprocated by data from another study conducted in a community pharmacy in the Midwest.[4] Over an 18-month time span, refilled medication checking rates were observed with accuracy rates of 99.73% and 99.45% ($p = 0.484$) between pharmacists and technicians respectively. The study also revealed an 18.72% net decrease in pharmacists' time spent in dispensing-related activities (from 67.3% to 48.58%, $p = 0.004$) and a 19.18% net increase in pharmacists' time spent providing patient care services (from 15.9% to 35.08%, $p = 0.002$). Therefore, data from this study also support the practical benefits for implementing TCT programs.

Limited literature is available regarding TCT in the community pharmacy setting within the United States. To date, there have been 11 publications regarding TCT. However, only four were specific to community settings. Of those four studies, only the two studies discussed above were conducted within the United States. This is a potential area of concern as the majority of literature supporting the implementation of TCT programs are robust for hospital institutions but lacking for community based pharmacies.[5]

While there are potential benefits of implementing TCT programs, community pharmacists may also wonder if the time from prescription verification would be redirected towards advanced clinical care or if their time may be cut in favor of less-expensive labor.[6] In fact, one of the original arguments for initiating TCT was rooted in cost reductions by shifting work hours from a pharmacist to a senior technician.[7] There are also concerns for increased liability for the pharmacist despite the current literature suggesting similar prescription verification accuracy rates.[6]

Pharmacy leaders have already identified that there is a need for a national standard of prerequisite training

in order to expand technician roles to include TCT.[8] As of March 2019, the Pharmacy Technician Certification Board (PTCB) announced plans to implement a Technician Product Verification (Tech-Check-Tech) assessment-based certificate program. This certification is proposed to be available as early as 2020.[9]

In conclusion, the implementation of TCT remains a topic of debate within the pharmacy profession. Additional studies in the community setting are needed to investigate issues such as workflow concerns and accuracy of verification long-term (studies looking at data collection greater than four weeks). Literature describing best practices and pearls to implementation of a TCT program in a variety of community settings (independent, chain, hospital outpatient pharmacies) would also be useful. In addition, the profession may benefit from determining what specific services pharmacists would be able to provide if prescription verification was delegated to technicians. Further studies or additional research is needed to determine if the TCT program will be beneficial to pharmacists across all setting.

REFERENCES

1. Gaither CA, Schommer JC, Doucette WR, Kreling DH, Mott DA. 2014 National Pharmacist Workforce Survey. AACP's 2014 National Pharmacist Workforce Study. https://www.aacp.org/sites/default/files/finalreportofthenationalpharmacistworkforcestudy2014.pdf Updated April 8, 2015. Accessed May 26, 2019.
2. Frost TP, Adams AJ. Expanded pharmacy technician roles: accepting verbal prescriptions and communicating prescription transfers. *Res Social Adm Pharm*. 2017 Nov; 13(6): 1191-1195.
3. Fleagle Miller R, Cesarz J, Rough S. Evaluation of community pharmacy tech-check-tech as a strategy for practice advancement. *J Am Pharm Assoc*. 2018;58(6):652-658.
4. Frost TP, Adams AJ. Tech-Check-Tech in Community Pharmacy Practice Settings. *J Pharm Technol*. 2017; 33(2):47-52
5. Frost TP, Adams AJ. Pharmacist and Technician Perceptions of Tech-Check-Tech in Community Pharmacy Practice Settings. *J Pharm Pract*. 2018;31(2):190-194.
6. Shane R. Advancing technician roles: an essential step in pharmacy practice model reform. *Am J Health Syst Pharm*. 2011;68(19):1834-5.
7. Adams AJ. Advancing technician practice: Deliberations of a regulatory board. *Res Social Adm Pharm*. 2018;14(1):1-5.
8. Wilson D. Review of Tech-Check-Tech. *J Pharm Technol*. 2003;19(3):159-169
9. Humphrey L. PTCB Developing Advanced CPhT Credential. *PTCB*. Published March 19, 2019. Accessed June 13, 2019. https://www.ptcb.org/about-ptcb/news-room/news-landing/2019/03/19/ptcb-developing-advanced-cpht-credential#.XQMz56Z7k_U

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Clinical Updates on Outpatient Treatment Options for Acute Uncomplicated Influenza

Jessica Krummel, PharmD Candidate 2020

Kathleen J Pincus, PharmD, BCPS, BCACP, University of Maryland School of Pharmacy

Learning Objectives

After completing this activity, the pharmacist will be able to:

1. Describe the impact of influenza on the United States healthcare system
2. Identify patients that are eligible to be treated for acute uncomplicated influenza with outpatient anti-influenza medications
3. Explain the mechanisms of action for oseltamivir (Tamiflu), zanamivir (Relenza), and baloxavir marboxil (Xofluza)
4. Develop appropriate treatment regimens including dosage, frequency, and duration for oseltamivir, zanamivir, and baloxavir marboxil

After completing this activity, the pharmacy technician will be able to:

1. Describe the impact of influenza on the United States healthcare system
2. Identify appropriate treatment regimens including dosage, frequency, and duration for oseltamivir, zanamivir, and baloxavir marboxil

Keywords

Influenza, Xofluza, Tamiflu, Relenza

Background

Influenza, commonly known as "the flu," is a virus that affects millions of Americans each year, with severity ranging from mild symptoms to death. Between 2010 and 2018, the Centers for Disease Control and Prevention (CDC) estimated there were between 9.3 and 49 million cases of the flu each year, despite the availability of effective flu vaccines.[1] In these eight years, flu cases resulted in 140,000–960,000 hospitalizations and 12,000–79,000 deaths.[1] In addition to these direct impacts on the healthcare system, influenza infections cause a substantial economic burden. Using data from the 2015 flu season, it was estimated that the influenza virus resulted in $3.2 billion in direct costs and $8 billion in indirect costs.[2] Furthermore, loss of productivity and absenteeism while suffering from the flu impacts society by preventing individuals from completing their respective duties in the workforce. It has been reported that people suffering from the flu, on average, miss 69% of expected work time once they start experiencing symptoms.[3] Due to these impacts, fast and effective treatment of influenza infection is crucial.

Influenza Virus

The influenza virus is an enveloped virus that contains a segmented negative-sense single-stranded RNA genome.[4] The human immune system has the ability to produce its own antibodies to eliminate specific influenza strains once exposed through infection or vaccination. However, there are new strains constantly being produced due to a process called antigenic drift. During this process the virus' polymerase creates errors while copying its own genome.[4] Due to antigenic drift, a new flu vaccine covering specific strains is recommended each year. In the United States, the majority of influenza illnesses occur between December and March.[5] There are two types of influenza virus, types A and B. Type A typically causes the influenza epidemics most people are familiar with, while type B is associated less frequently with infections.[5] When patients become infected with the influenza virus, they can present with a number of symptoms varying in severity, including: fever greater than 102°F, headache, muscle aches, cough, and sore throat.[5] Usually, patients will recover from an influenza infection in less than two weeks by utilizing the antibodies their body makes naturally.[14] However, sometimes an infection with

the influenza virus can lead to complications, such as pneumonia, that lead to hospitalization.[14] This is especially problematic for high-risk populations. People at high-risk for complications include individuals that are 65 years of age or older, those with chronic medical conditions such as asthma, diabetes, or heart disease, pregnant patients, and children younger than five years of age.[14]

The natural antibodies produced by the immune system mainly target two key proteins located on the surface of the influenza virus.4 These proteins are hemagglutinin (HA) and neuraminidase (NA). Viral NA primarily functions to prevent aggregation of viral particles. It also prevents the virus from sticking to host cells it has already killed.[4] These two functions allow for the spread of newly made virus particles to new human host cells. When a natural antibody or medication inhibits the function of viral NA, the virus can no longer spread, eventually eliminating all invading viral particles. Another enzyme necessary for influenza viral replication is viral polymerase, a protein containing three subunits.[6] One of the three subunits is the polymerase acidic (PA) protein. This protein is responsible for initiating the viral genome transcription process by cleaving nucleotides via endonuclease activity.[6] Traditional outpatient anti-influenza treatments target the NA protein.[7,8] These medications inhibit the function of viral NA, stopping the virus' ability to spread. However, newer anti-influenza medications inhibit the endonuclease activity of the viral PA protein, and therefore, inhibits the virus' ability to replicate.[9]

Treatment Options

The most efficient way of avoiding the negative effects of the influenza virus is to prevent it from occurring. Each year, a flu vaccine is used to accomplish this. Despite this, influenza illness continues to make a large impact on the healthcare system. Currently, there are three FDA-approved medications that are recommended for the outpatient treatment of acute uncomplicated influenza by the CDC [Table 1]. Oseltamivir (Tamiflu) and zanamivir (Relenza) are both NA inhibitors while baloxavir marboxil (Xofluza) is a PA protein inhibitor. These treatments may decrease the amount of time patients experience symptoms, lessen the severity of symptoms, and prevent the spread of the virus to other individuals.[5] Other FDA-approved medications include amantadine (Symmetrel), rimantadine (Flumadine), and peramivir (Rapivab). However, these are not currently recommended for the outpatient treatment of acute uncomplicated influenza by the CDC. Resistance has rendered amantadine and rimantadine inadequate, and peramivir is an intravenous medication used inpatient only.[5]

Oseltamivir (Tamiflu)

Oseltamivir was originally approved by the FDA in 1999 and is currently indicated for the for the treatment of acute uncomplicated influenza, if given within 48 hours of the start of symptoms.[7] It is also indicated for the prevention of acute uncomplicated influenza.[7] For the treatment of influenza, oseltamivir can be used in patients

Table 1. Comparison of Available Outpatient Anti-Influenza Medications

	Oseltamivir	Zanamivir	Baloxavir marboxil
Indication for Acute Uncomplicated Influenza	**Treatment & Prophylaxis**	**Treatment & Prophylaxis**	**Treatment**
Treatment Dosing	75mg twice daily for 5 days	Two 5mg inhalations twice daily for 5 days	*40–79kg:* two 20mg tablets for one dose *>80kg:* two 40mg tablets for one dose
Prophylaxis Dosing	75mg once daily for 10 days	Two 5mg inhalations once daily for 10 days	–
Age Restrictions	Treatment: > 2 weeks Prophylaxis: > 1 year	Treatment: > 7 years Prophylaxis: > 5 years	Treatment: > 12 years
Time to Treat	48 hours	48 hours	48 hours
Generic Available	Yes	No	No
Route of Administration	Oral Capsule	Oral Inhalation	Oral Tablet
Duration of Treatment	Treatment: 5 days Prophylaxis: 10 days	Treatment: 5 days Prophylaxis: 10 or 28 days	Treatment: 1 dose, 1 day
Reduction in Median Time to Symptom Improvement	1.3 days	1.5 days	1.1–1.2 days

two weeks of age or older, with weight-based dosing for children under 13 years old.[7] Patients 13 years of age and older can be given one 75mg capsule by mouth twice daily for five days.[7] To prevent an influenza infection after suspected contact with an infected person, adults and adolescents 13 years of age and older can take one 75mg capsule by mouth once daily for at least 10 days.[7] A summary of these dosing regimens can be found in Table 1. Dose adjustments are necessary for patients with moderate or severe renal impairment. Oseltamivir is available as a generic and is packaged in quantities of ten to accommodate the total number of doses needed for treatment and prophylaxis regimens. Each package of ten 75mg capsules has an average wholesale price (AWP) of $140.[10] A liquid suspension of 6mg/mL can be used for both indications if oral capsules cannot be tolerated.[7]

Results from two placebo-controlled, double-blind clinical trials found that when the recommended dose of oseltamivir was given within 40 hours of symptom onset, there was a reduction in the median time to symptom improvement of 1.3 days when compared to placebo.[7] Nausea and vomiting are the most common adverse reactions experienced by patients taking oseltamivir, occurring in nine to ten percent of patients.[7] It is not necessary to take oseltamivir with food, but doing so may improve tolerability.[7] Other adverse effects seen in more than 1% of patients include[7]:

- diarrhea
- bronchitis
- abdominal pain
- dizziness
- headache
- cough
- insomnia
- vertigo
- fatigue

Some serious side effects have been reported in patients taking

Active Learning – Patient Case

Alexander Miller is a 25-year-old male (72 inches, 160 lb., NKDA) who presents to your community pharmacy this evening to pick up a new prescription for Xofluza. He is complaining of body aches and a fever, both of which started a day and a half ago. Mr. Miller is usually a healthy man who takes no prescription medications but takes ibuprofen for an occasional headache and a daily multivitamin.

1. Is AM a candidate for treatment with Xofluza?

a. Yes, his symptoms started less than 48 hours ago

b. Yes, he has no chance of experiencing drug interactions and has no contraindications

c. No, he takes a daily multivitamin which may contain substances that interfere with the absorption of this medication

d. No, he has a contraindication to taking Xofluza

2. What is an appropriate dose of Xofluza for AM?

a. One 40mg tablet for one dose

b. One 20mg tablet taken every twelve hours for two doses

c. Two 20mg tablets taken as one dose

d. Two 40mg tablets taken as one dose

3. What counseling should AM receive regarding his diet while taking Xofluza?

a. Xofluza should be taken without food

b. Xofluza should not be taken with fruit juices, including grapefruit juice.

c. Xofluza should not be taken with dairy products, calcium-fortified foods or beverages, antacids, or supplements containing calcium, iron, magnesium, selenium, or zinc.

d. Xofluza should be taken with at least a full 8 oz. glass of water

4. What counseling should AM receive regarding the possible side effects of Xofluza?

a. Patients may experience ringing in the ears while taking this medication

b. Patients may experience diarrhea or a headache while taking this medication

c. Patients will likely experience nausea while taking this medication

d. Patients may experience photosensitivity while taking this medication

5. When should AM be instructed to take this medication?

a. AM should wait to take his Xofluza until he has the chance to eat a meal

b. AM should take his Xofluza immediately

c. AM should wait to take his Xofluza until tomorrow morning when he has an empty stomach

d. None of the above

Answers on page 14

oseltamivir, including anaphylaxis, toxic epidermal necrosis, Stevens-Johnson Syndrome, and erythema multiforme.[7]

Zanamivir (Relenza)

Zanamivir was also approved by the FDA in 1999 and is currently indicated for the for the treatment of acute uncomplicated influenza, if given within 48 hours of the start of symptoms.[8] It is also indicated for the prevention of acute uncomplicated influenza.[8] For the treatment of acute uncomplicated influenza, patients seven years and older should inhale two 5mg doses twice daily for a total of five days.8 For prophylaxis in a household setting, patients five years and older should inhale two 5mg doses once daily for ten days.[8] Patients can follow the same dosing instructions for prophylaxis in a community outbreak situation, but should continue the regimen for a total of 28 days.[8] Zanamivir is formulated as an oral inhalation powder and is only available as a branded product.[8] Each package contains one DISKHALER inhalation device and five ROTADISKs, which each contain four 5mg doses of inhalation powder.[8] This is sufficient for a full treatment regimen. The AWP per package of zanamivir is $70.80.[11] Detailed instructions for use of the inhalation device are available in the package insert and include loading the medication into the inhalation device. Zanamivir is not recommended for patients with underlying airway disease due to potential side effects that may exacerbate their condition, such as bronchospasm.[8]

Zanamivir's clinical efficacy trials showed mixed results. Clinical trial results showed the median time to symptom improvement was reduced by up to one day, compared to placebo; however, these results were not statistically significant.[8] They also report that additional trials in the southern hemisphere observed a reduced median time to symptom improvement of 1.5 days.[8]

The most common adverse reactions in patients 12 years and older are[8]:

- Headache
- diarrhea
- nausea
- vomiting
- bronchitis
- cough
- sinusitis
- dizziness
- ear, nose, and throat infections.

Some serious adverse events were also reported from patients taking zanamivir, which include bronchospasm and allergic-like reactions such as oropharyngeal edema, serious skin rashes, and anaphylaxis.[8]

Baloxavir Marboxil (Xofluza)

Baloxavir marboxil was approved by the FDA in 2018 and is currently indicated for the treatment of acute uncomplicated influenza in patients twelve years of age and older and symptomatic for less than 48 hours.[9] Baloxavir marboxil is available as an oral tablet and is only available in brand.medication.[12] It can be taken with or without food, but patients should be advised to avoid administering at the same time as cations (e.g. calcium, iron). There are currently no recommendations on how long to separate baloxavir marboxil from cation containing foods and medications. Baloxavir marboxil is taken as a single dose consisting of two tablets.[9] Patients weighing between 40-79 kg, should take two 20mg tablets by mouth as a single dose. If a patient weighs more than 80 kg, two 40mg tablets taken by mouth as one dose is recommended. Baloxavir marboxil is packaged as two tablets, which is sufficient to complete a full treatment regimen, and each strength has an AWP of $150.00 per package.[12] Of note, Genetech has discontinued their previously offered Xofluza coupon program that helped patients afford the medication.

A clinical trial reports that baloxavir marboxil produced a statistically significant lower time to symptom resolution than placebo.[15] In a phase II trial, participants received either a 10mg, 20mg, or 40mg dose of baloxavir marboxil or placebo. In this trial, the 40mg treatment group saw a resolution of symptoms in 49.5 hours, compared to the placebo group that saw symptom resolution in 77.7 hours.[15] This is approximately equivalent to 1.2 fewer days less with symptoms. In a phase III trial, patients were randomized to receive 40mg baloxavir marboxil, 80mg baloxavir marboxil, or placebo.[9] Time to symptom resolution was 53.7 hours in both treatment groups while patients receiving placebo had a resolution of symptoms in 80.2 hours.[15] This is approximately equivalent to 1.1 fewer days with symptoms present.

The most common side effects experienced by patients taking baloxavir marboxil are[9]:

- diarrhea
- nausea
- bronchitis
- nasopharyngitis
- headache.

However, none of these adverse effects were more common than effects reported in the placebo group.[9] Since baloxavir marboxil has only been on the market for such a relatively short time, post-marketing adverse events have not been reported yet.

Clinical Use

With a new agent recently entering the market, clinicians will face uncertainty when making clinical decisions on which agent to use to best treat their patients. Since all three agents have a similar outcome of reducing symptoms by approximately one day, the most important things to consider when selecting an agent are side effect profile, ease or convenience of use, and cost to the patient. Of note, baloxavir marboxil is approved for treatment only and not prophylaxis, while oseltamivir and zanamivir are approved for both treatment and

prophylaxis. Approval also varies among the three agents in regard to minimum age of approved use, with oseltamivir approved for children as young as two weeks old.

Patients who are pregnant are at a higher risk for complications due to the influenza virus, and therefore should be treated more cautiously.[14] However, making a clinical decision regarding treatment for a woman who is pregnant and also suffering from an influenza virus can be complex because all three agents have limited clinical data regarding the safety of use during pregnancy. Since baloxavir marboxil is the newest agent and has the least amount of data available, the CDC recommends against the use of this agent in the pregnant population.[13] The data available for oseltamivir, although limited by small sample sizes and scarce dose information, does not suggest that oseltamivir is linked with an increased risk for birth defects.[7] In fact, oseltamivir is the agent recommended for use in pregnancy by the CDC.[13] The dosing and duration of treatment for pregnant women should be the same as non-pregnant patients.[13] The CDC does not make any specific recommendations in regard to zanamivir. The manufacturer of zanamivir advises that there is insufficient data regarding use in pregnancy and the medication should only be used if the clinician believes the potential benefit outweighs the potential risk.[13, 8]

When comparing all three agents, baloxavir marboxil appears to have the best side effect profile because the adverse effects experienced by treatment groups were similar to the placebo group.[9] However, as the drug spends more time on the market, new or serious side effects may emerge. Both oseltamivir and zanamivir have similar side effect profiles with some of the most common side effects being nausea, vomiting, diarrhea, and headache.[7,8] These side effects are not uncommon for medications that treat infections and should not deter clinicians from utilizing these medications. Patients with lung disease should avoid zanamivir as the inhaled route of administration has the potential to trigger bronchospasms in those predisposed.

Adherence to medications used to treat infections is particularly important for the success of the regimen. Therefore, it is important to consider ease of administration and likelihood of a patient's ability to complete a full course of therapy. An inhaled medication, like zanamivir, relies on the patient's ability to be able to correctly use an inhalation device. Additionally, a course of zanamivir involves the patient inhaling medication twice daily for five days. Oseltamivir is also a five-day course of treatment that needs to be taken twice daily; however, oseltamivir is a capsule, which may be a more convenient and reliable dosage form when compared to an inhaled medication. Baloxavir marboxil is a one-time oral dose. Patients would likely adhere better to a one-time dose compared to medications that have to be taken twice daily for five days.

Lastly, in order for patients to adhere to a medication regimen, they need to be able to afford it. Oseltamivir is the only one out of the three treatment options that is available generically, and may therefore be a preferred option by commercial insurers. For patients paying out of pocket, Relenza has

ANSWERS

1. **Answer: A.** Treatment is only indicated for patients if their symptoms have been occurring for less than 48 hours [Answer A is correct]. AM has a potential drug-drug interaction between baloxavir marboxil (Xofluza) and his daily multivitamin [Answer B is incorrect]. However, baloxavir marboxil can still be used if the patient is counseled to separate his baloxavir marboxil from his daily multivitamin [Answer C is incorrect]. The only contraindication for Xofluza is hypersensitivity to baloxavir marboxil or any other ingredients in Xofluza [Answer D is incorrect].
2. **Answer C.** For patients that are 12 years of age and older, with no contraindications, and weighing between forty and eighty kilograms, the correct dosing is two 20mg tablets taken by mouth once for one dose. Although giving one 40mg tablet would be an equivalent dose, the medication has only been studied as two 20mg tablets. [Answer C is correct, Answers A, B, and D are incorrect]
3. **Answer: C.** Baloxavir marboxil can be taken with or without food [Answer A is incorrect] and has no dietary restrictions with the exception of dairy products, calcium-fortified foods or beverages, antacids, or supplements containing calcium, iron, magnesium, selenium, or zinc due to the potential of cations to bind drug product [Answer C is correct]. Baloxavir marboxil does not have known interactions with CYP3A4 inhibitors including grapefruit juice [Answer B is incorrect]. Baloxavir marboxil does not require a specific amount of water for administration [Answer D is incorrect].
4. **Answer B.** Adverse effects reported by the manufacturer include diarrhea, nausea, bronchitis, nasopharyngitis, and headache [Answer B is correct]. All adverse effects reported by the manufacturer occurred in less than 3% of patients, and none occurred more frequently than the placebo group [Answer C is incorrect]. Tinnitus and photosensitivity have not been reported with use [Answer A and D are incorrect].
5. **Answer B.** Baloxavir marboxil may be taken with or without food [Answers A and C are incorrect]. The time to treatment effects the efficacy of baloxavir marboxil, so patients should take the medication as soon as possible [Answer B is correct].

the lowest AWP at $70.80 per course of therapy.[11] It will be important for pharmacists to review a patient's insurance coverage and recommend an appropriate agent if the product initially selected is not covered.

The decision to treat an influenza infection will need to be individualized for each patient. As always, clinicians should weigh the potential benefits of treating their patients against the potential risks. If a patient presents within the recommended time frame or is at high-risk for complications, they will likely benefit from these medications by reducing their symptoms by approximately one day and by reducing their risk for complications that may lead to hospitalization or death. However, if a patient's symptoms are mild, they have had symptoms for more than 48 hours, or are not at high risk for complications, it may be appropriate to not treat the patient.

Summary

Millions of patients suffer from infection with the influenza virus each year causing a significant economic burden on the healthcare system and society. Additionally, patients suffering from the flu miss work and experience decreased productivity. Despite having effective flu vaccines each year, the United States still experiences negative effects of this ever-changing virus. However, medications currently available can help reduce patient's symptoms by helping them recover faster, reducing the burden on the healthcare system, but most importantly on the patient. ●

REFERENCES

1. Centers for Disease Control and Prevention. Disease Burden of Influenza. https://www.cdc.gov/flu/about/burden/index.html. Accessed June 1, 2019.
2. Wayan C.W.S. Putri et al. Economic Burden of Seasonal Influenza in the United States. *Vaccines*.2018;(36)3960-3966.doi:10.1016/j.vaccine.2018.05.057
3. Jeffrey J. Van Wormer et al. Influenza and Workplace Productivity Loss in Working Adults. *Journal of Occupational and Environmental Medicine*.2017.59(12)1135-1139.doi:10.1097/JOM.0000000000001120
4. Julie L. McAuley et al. Influenza Virus Neuraminidase Structure and Functions. *Frontiers in Microbiology*. 2019. Doi:10.3389/fmicb.2019.00039
5. Alldredge et al. Infectious Disease. In: Koda-Kimble & Young's Applied Therapeutics: The Clinical Use of Drugs. 10th ed. Philadelphia, Pennsylvania: Lippincott Williams & Wilkins; 2013:1782-1783
6. Satoshi Fudo et al. Two Distinctive Binding Modes of Endonuclease Inhibitors to the N-Terminal Region of Influenza Virus Polymerase Acidic Subunit. *Biochemistry*.2016;55(18):2646-2660. doi:10.1021/acs.biochem.5b01087
7. Tamiflu [package insert]. San Francisco, CA: Genentech; 2018.
8. Relenza [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2018.
9. Xofluza [package insert]. San Francisco, CA: Genentech; 2018
10. AWP Pkg Price: Oseltamivir Phosphate. RED BOOK Online. Micromedex Healthcare Series [database online]. Ann Arbor, MI: Truven Health Analytics. Accessed June 26, 2019.
11. AWP Pkg Price: Relenza. RED BOOK Online. Micromedex Healthcare Series [database online]. Ann Arbor, MI: Truven Health Analytics. Accessed June 26, 2019.
12. AWP Pkg Price: Xofluza. RED BOOK Online. Micromedex Healthcare Series [database online]. Ann Arbor, MI: Truven Health Analytics. Accessed June 26, 2019.
13. Centers for Disease Control and Prevention. Influenza Antiviral Medications: Summary for Clinicians. https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm.https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm. Accessed June 22, 2019.
14. Centers for Disease Control and Prevention. Flu Symptoms & Complications. https://www.cdc.gov/flu/symptoms/symptoms.htm.https://www.cdc.gov/flu/symptoms/symptoms.htm. Accessed June 22, 2019
15. Fredrick G. Hayden et al. Baloxavir Marboxil for Uncomplicated Influenza in Adults and Adolescents. *The New England Journal of Medicine*. 2018. doi: 10.1056/NEJMoa1716197finalreportofthenationalpharmacistworkforcestudy2014.pdf Updated April 8, 2015. Accessed May 26, 2019.

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(1) Enter your name and contact information.

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Editorial

Do You Have the Flu?
Let the Pharmacy Be Your New Point-of-Care

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Department of Pharmacy Practice and Science, University of Maryland School of Pharmacy

Disclosure: Nothing to disclose

Introduction

The United States is currently experiencing its yearly epidemic — also known as "flu season." Influenza activity starts as early as August and often peaks between December and February, but many may not know that the flu season can continue until May.[1] Prompt identification and treatment of the flu is important to prevent complications. Pharmacists are highly accessible providers and have an opportunity to provide screening for cases of influenza in the community.

Point-of-Care Testing

There are a variety of point-of-care (POC) tests that pharmacists can provide, including screening and monitoring for chronic diseases and detecting acute infectious diseases.[2] These tests allow patients to receive rapid and reliable results in a convenient setting and improve access to care. In order to perform POC testing, pharmacists must obtain a certificate of waiver from the Centers for Medicare and Medicaid Services (CMS) and pay any applicable certificate fees biennially.[2] Furthermore, state-required fees and permits may also apply.[2] In Maryland, pharmacies performing only excepted tests, such as influenza A/B or group A Streptococcal infection screenings, may obtain a letter of exception rather than a permit.[3] Once these requirements are completed, the pharmacist can operate tests waived under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).[2]

Rapid Influenza Diagnostic Tests

Influenza POC testing within community pharmacies provide a highly accessible and rapid method of screening patients for the flu. This can reduce time from symptom onset to initiation of antivirals. Prompt diagnosis and treatment may also help to reduce inappropriate antibiotic use for misdiagnosed respiratory infections or influenza complications.

How Do They Work?

Rapid Influenza Diagnostic Tests (RIDTs) are immunoassays that detect influenza antigens within a sample.[4] The presence of these viral antigens, typically nucleoproteins, activate a color change or other visual signal.[4] This occurs when the antigens bind to anti-influenza antibodies on the test strip and migrate to the reaction area.[4] Most RIDTs distinguish between strains and may have distinct areas for indicating presence of influenza A or B on the test strip. Some tests utilize digital reader devices which allows for standardization of interpretation of results.[5]

Specimen Collection

Different tests may accept a variety of respiratory samples such as nasal washes or swabs, nasopharyngeal aspirates or swabs, nasal aspirates, or throat swabs.[4] Thus, it is important to be sure that the specimen collected is compatible with the device (Table 1). Specimens should be collected as soon as possible after symptom onset, ideally within 3 to 4 days. After collection, the samples should be tested immediately with results typically taking 10 to 15 minutes to appear.[4]

Efficacy and Interpretation of Results

Effective in 2018, the U.S. Food and Drug Administration (FDA) reclassified RIDTs from class I to class II devices, requiring more stringent minimum standards for sensitivity and specificity.[5] RIDTs must now achieve 80% to 90% sensitivity and 95% specificity compared to reverse transcriptase polymerase chain reaction (RT-PCR) and viral culture testing.[5] Test accuracy is influenced by a wide range of factors including influenza type or subtype due to antigen structure variation, amount of virus present in collected specimen, quality and source of sample, collection technique and interpretation skills, use of unauthorized collection tools, and improper or prolonged storage.[4,5] Additionally, tests that utilize digital analysis instruments have higher sensitivities.[5] It is also important to consider the prevalence of influenza in the

Table 1. CLIA-waived FDA-Cleared Rapid Influenza Diagnostic Tests[8,9,10]

Manufacturer	Product	Instrument	Time to Results (min)[a]	Approved Specimensa
Abbott	BinaxNOW® Influenza A&B Card 2	DIGIVAL[b]	15	NPS, NS direct
	ID NOW™ Influenza A&B	ID NOW™	5-13	NPS direct or in VTM, NS direct or in VTM
Becton Dickinson & Co.	BD Veritor™ Flu A+B	BD Veritor Reader	10	NPS, NS direct
		BD Veritor Plus Analyzer	10	
Quidel Corp.	Sofia® Influenza A+B FIA	Sofia FIA Analyzer	15	NS, NPS, NPA, NPW direct, NP, NPA, NPW in VTM
		Sofia 2 FIA Analyzer	3-15	
	QuickVue® Influenza A+B	N/A	10	NPS, NS direct
Princeton BioMeditech Corp.	BioSign® Flu A&B	N/A	10-15	NS, NPS direct
	LifeSign LLC Status Flu A&B			
	OraSure QuickFlu Rapid A+B			
	LABSCO Advantage Flu A&B			
	Polymedco Poly stat Flu A&B			
	Sekisui Diagnostics OSOM Ultra Flu A&B			
	Meridian BioScience ImmunoCard STAT Flu A&B			
	McKesson Consult Diagnostics Influenza A&B			

A = aspirate; N = nasal; N/A = RIDT does not use analyzer device; NP = nasopharyngeal; S = swab; VTM = viral transport media; W = wash
[a]Information from product package inserts and manufacturer' websites
[b] Approved 7/1/2019; Formerly Alere Reader

community when interpreting results. When influenza prevalence is low there is a higher chance for false-positives.[5] Conversely, during peak flu season when influenza activity is high, false-negative results are more likely to occur, with rates of 6% to 7% despite high test sensitivities (90%).[5]

Disadvantages

There are some disadvantages to RIDTs that need to be considered. RIDTs are not recommended for hospitalized patients, instead molecular assays such as RT-PCR are used.[5] Additionally, tests are not able to provide subtype information, and there is no capability to provide antiviral susceptibility information.[5,6] There is also the additional effort of obtaining certifications, providing training, and equipment costs. Lastly, due to the potential for false results depending on viral prevalence at the time of testing, a negative result cannot always rule out influenza. Therefore, it is especially important to consider the clinical presentation of each patient being tested.

Conclusions

Influenza POC testing provides many benefits to patients such as increased accessibility to influenza testing and convenience. This can have an important impact on appropriate and effective patient care. RIDTs can also assist with gathering data for surveillance of prevalence and incidence of influenza, and promote partnerships among health care providers through the implementation of collaborative practice agreements (CPA).[6] CPAs allow pharmacists and physicians to create protocols for prescribing and dispensing influenza antivirals when the patient meets the criteria of the protocol.[7] In Maryland, a CPA with a provider would be necessary for pharmacists to dispense antivirals to the patient at the time of testing. Alternatively, pharmacists without CPAs could consult the patient's primary care physician to develop a treatment plan, such as dispensing antivirals, symptomatic treatment, or referring to the physician's office or emergency room as

appropriate. Ultimately, incorporation of influenza POC testing in community pharmacies could lead to reduction of unnecessary or inappropriate antimicrobial use and increased patient satisfaction.[6]

REFERENCES

1. Frequently Asked Flu Questions 2018-2019 Influenza Season. Centers for Disease Control and Prevention. https://www.cdc.gov/flu/about/season/flu-season-2018-2019.htm.
2. Point-of-Care (POC) Testing. National Community Pharmacists Association. https://www.ncpanet.org/innovation-center/diversified-revenue-opportunities/point-of-care-(poc)-testing.
3. Code of Maryland Regulations. 10.10.03.02.
4. World Health Organization. *Use of Influenza Rapid Diagnostic Tests*. Geneva: WHO. https://www.who.int/influenza/resources/publications/influenza_rapid_test/en/.
5. Rapid Diagnostic Testing for Influenza: Information for Clinical Laboratory Directors. Centers for Disease Control and Prevention. https://www.cdc.gov/flu/professionals/diagnosis/rapidlab.htm.
6. Gubbins PO, Klepser ME, Dering-Anderson AM, et al. Point-of-care testing for infectious diseases: Opportunities, barriers, and considerations in community pharmacy. *Journal of the American Pharmacists Association*. 2014;54(2):163-171. doi:10.1331/japha.2014.13167
7. Klepser ME, Klepser DG, Dering-Anderson AM, Morse JA, Smith JK, Klepser SA. Effectiveness of a pharmacist-physician collaborative program to manage influenza-like illness. *Journal of the American Pharmacists Association*. 2016;56(1):14-21. doi:10.1016/j.japh.2015.11.008
8. Rapid Influenza Diagnostic Tests (RIDTs). Centers for Disease Control and Prevention. https://www.cdc.gov/flu/professionals/diagnosis/table-ridt.html#ft2.
9. Azar MM, Landry ML. Detection of Influenza A and B Viruses and Respiratory Syncytial Virus by Use of Clinical Laboratory Improvement Amendments of 1988 (CLIA)-Waived Point-of-Care Assays: a Paradigm Shift to Molecular Tests. *Journal Of Clinical Microbiology*. 2018;56(7). doi:10.1128/JCM.00367-18.
10. CLIA - Clinical Laboratory Improvement Amendments. Food and Drug Administration. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/results.cfm

Maryland Health Ranking

Maryland ranks nineteenth overall, a three-place fall from sixteenth last year

BEHAVIORS — Ranked 10th

Category includes everything from physical activity (24), to excessive drinking (10), to drugs deaths (41), to smoking (8), to obesity (25).

COMMUNITY & ENVIRONMENT — Ranked 25th

Category includes violent crime (40), children in poverty (6), infectious disease (21), and pertussis (11).

POLICY — Ranked 11th

We rose six points in 2018. We climbed three points in immunizations for adolescents (18), and six points in immunizations for children (11) and gained 13 points with our numbers of meningococcal immunizations (10).

CLINICAL CARE — Ranked 17th

Category includes primary care physicians (8) and mental health providers (24). We improved our ranking by five points in the number of low birthweights (30).

OUTCOMES — Ranked 27th

Falling one point from 2017, we ranked near the middle in both Disparity in Health Status and Premature Death (28 each) but showing a 10-point rise in diabetes.

For more information, visit www.americashealthrankings.org.

Editorial

Third Quarter: Pharmacy Time Capsule

By: Dennis B. Worthen, PhD, Cincinnati, OH

1994

- Third Pharmacy in the 21st Century held in Leesburg, VA with the objective of seeking strategies to overcome barriers to pharmaceutical care.

1969

- President Richard Nixon calls for a national anti-drug policy at the state and federal level and identifies drug abuse as "a serious national threat."

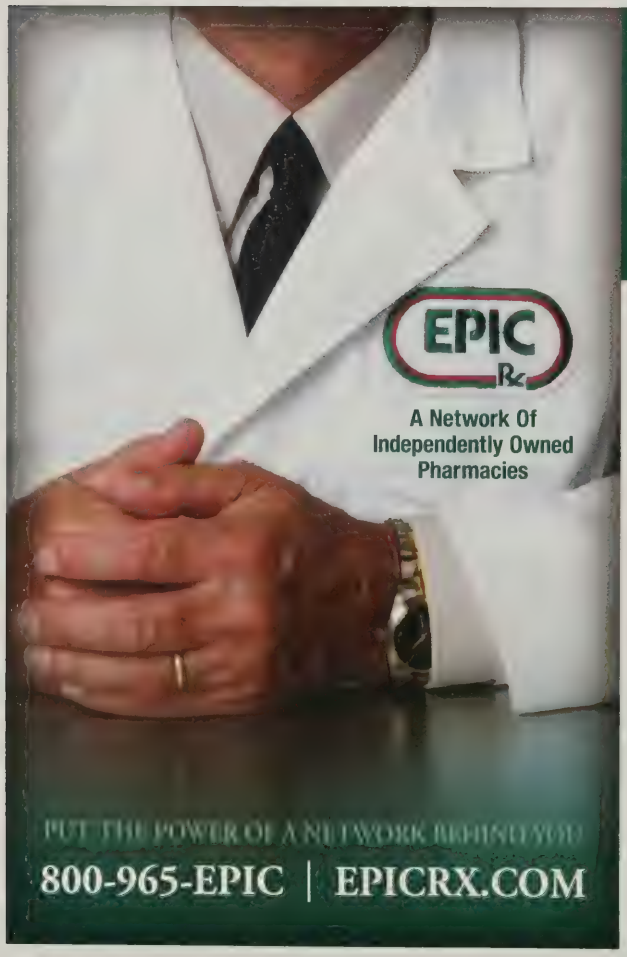
1944

- The creation of Coppertone is usually credited to Benjamin Green, a pharmacist in the US Army Air Forces, who developed the prototype during WW II.

1919

- Ratification of the 18th amendment to the United States constitution, prohibiting the manufacture, sale, or transportation of intoxicating liquors. Special prescription blanks were required for alcohol.

One of a series contributed by the American Institute of the History of Pharmacy, a unique non-profit society dedicated to assuring that the contributions of your profession endure as a part of America's history. Membership offers the satisfaction of helping continue this work on behalf of pharmacy, and brings five or more historical publications to your door each year. To learn more, check out: ***www.aihp.org***



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SAVE THE DATE:
Sunday, February 16, 2020

2020 MPhA Mid-Year Meeting

College Park Marriott Hotel & Conference Center
3501 University Blvd. East
Hyattsville, MD 20783

Registration Rates

	Engaged/ Connected	Informed/ Non-Member
Pharmacist	$179	$229
Student/ Technician	$99	$149

Registration is now open at marylandpharmacist.org

MPhA
2020 MID-YEAR MEETING
FEBRUARY 16 · HYATTSVILLE

MPhA invites you to join us for a day of live continuing education and networking with your peers and colleagues.

Other Events:
House of Delegates • Closing Reception

Special Conference Room Rate: $128.00 per night

Deadline for Reservations: January 25, 2020

Call 301-985-7300 to make your reservation!

Interested in Sponsorship or Exhibiting?

Contact Lauren Williams at lauren.williams@mdpha.com or 443-583-8000.

Member Mentions & News You Can Use *continued from page 6*

MPhA Launches CBD Task Force

This year the House of Delegates passed several CBD-related policies, which can be viewed in the MPhA Policies posted on the website. The CBD Task Force is led by former Marijuana Cannabis Commissioner W. Christopher Charles and medicinal cannabis advocate Arnold Honkofsky will use the policies to guide their work.

MPhA's Call for Abstracts Being Accepted for Future CE Programs!

MPhA is currently seeking abstracts for future CE programs. You are encouraged to submit an abstract to share your knowledge and expertise with your peers. Innovative and engaging content will enhance the profession and the practice of pharmacy in Maryland. Submit abstract and learning objectives: https://tinyurl.com/y5hy7e5k.

MPhA *Welcomes* OUR NEWEST MEMBERS

Welcome to MPhA, we are happy to have you! If you meet these new members, please welcome them to the MPhA pharmily. Be sure to invite them to join a committee or attend a networking event!

Students

Hanna Neal – Baltimore
Gina Lee – Baltimore
Kristie Oh – Hanover
Sahar Salih – Jessup
Jose Munoz – Baltimore
Nastaran Aslinejad – Rockville

Engaged

Keely Ireland - Halethorpe
John King – North Chesterfield

Informed

Javon Lewis – Baltimore
Love Che – Laurel
Christopher Ford – Clinton
Christelle Ngatchou – Columbia
Sheena Williams – Baltimore
Donna Elhindi – Germantown
Farid Isreal – Columbia
Mulu Gizaw – Salisbury
Binyam Terera – Silver Spring
Saima Igbal – Fairfax
Kari Louk – Derwood
Min Tzu Chung – Oak Park
Hiang Dawley – Gambrills
Kurtis Dawley – Gambrills
Helen Ly
Alyanna Brown – Upper Marlboro

Connected

Michael Conti – Perry Hall

SAVE THE DATES IN YOUR 2019-2020 CALENDAR

Nov 21 — **Board of Trustees Meeting**

Dec 12 — **MPhA Holiday Party**

Jan 23 — **Board of Trustees Meeting**

Feb 6 — **Maryland Pharmacy Coalition Legislative Day**

Feb 16 — **2020 Mid-Year Meeting**

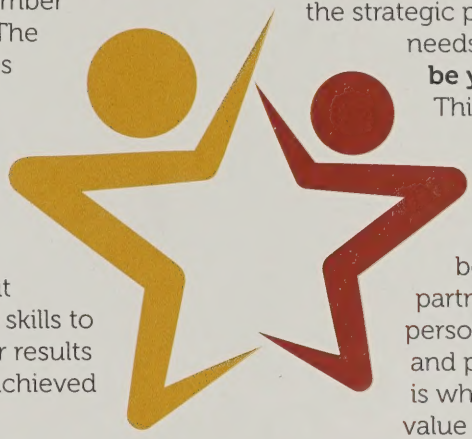
For more information and additional activities, visit www.marylandpharmacist.org.

Executive Director's Message

"With the new membership categories, it is easier than ever to explain benefits of membership and how someone can become an Informed, Engaged and Connected member of MPhA. Please spread the word. Imagine what we could accomplish if ALL licensed Maryland pharmacists were informed, engaged and connected partners in strengthening the profession, advocating for pharmacists and promoting excellence in pharmacy practice."

How Can MPhA Be a Better Partner?

When I was studying for the CAE (Certified Association Executive) credential, one of the recommended reference texts was, "The Power of Partnership," by Plexus Consulting Group. The publication was a joint research endeavor between the American Society of Association Executives and the US Chamber of Commerce. The publication goes through case studies of how separate entities can join together "to leverage their distinct but complimentary skills to produce greater results than could be achieved individually."



They outline five key reasons or benefits for cultivating partnerships:

1) Sharing of resources
2) Ability to reach broader markets
3) Advancing the organization's mission
4) Developing new ways of working
5) Gaining access to additional resources.

As we settle into another MPhA year, I think about how important partnerships have been to MPhA in 2019. This year through national and local partnerships we have passed critical PBM-related laws; pushed for expanded scope of practice and prescriptive authority; played a critical role in education on drug disposal and pharmacists' role in pain management; explored alternative payment models for pharmacist patient care services and a hosted several continuing education opportunities.

The Board of Trustees is embarking on a revamp of its strategic plan, to be presented at the 138th Annual Convention in June of 2020. During the next several months you will be asked to participate in guiding the strategic plan to meet your needs. **How can MPhA be your partner?** Think about the key benefits previously highlighted and about how MPhA has been or can be a better strategic partner to advance your personal, professional and practice goals. This is where MPhA adds value — but we can only do it through the power of your participation as members and partners.

With the new membership categories, it is easier than ever to explain benefits of membership and how someone can become an Informed, Engaged and Connected member of MPhA. Please spread the word. There are approximately 5,000 pharmacists who are licensed and live in the state of Maryland. Imagine what we could accomplish if ALL were informed, engaged and connected partners in strengthening the profession, advocating for pharmacists and promoting excellence in pharmacy practice.

We are *Stronger by Association,*

Aliyah N. Horton, CAE
Executive Director

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